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(54) DEVICE FOR ALTERNATELY HOLDING, OR EFFECTING RELATIVE LONGITUDINAL MOVEMENT, OF MEMBERS OF A MEDICAL INSTRUMENT

(75) Inventors: **James W. Voegele**, Cincinnati, OH (US); **Robert P. Gill**, Mason, OH (US); **Christopher J. Hess**, Cincinnati, OH (US); **William B. Weisenburgh II**, Maineville, OH (US)

Correspondence Address:
U.S. Docket Clerk
Johnson & Johnson Law Department
P.O. Box 1222
New Brunswick, NJ 08903 (US)

(73) Assignee: **Ethicon Endo-Surgery, Inc.**

(21) Appl. No.: **11/094,119**

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Related U.S. Application Data

(60) Provisional application No. 60/569,195, filed on May 7, 2004. Provisional application No. 60/582,302, filed on Jun. 23, 2004. Provisional application No. 60/639,836, filed on Dec. 28, 2004.

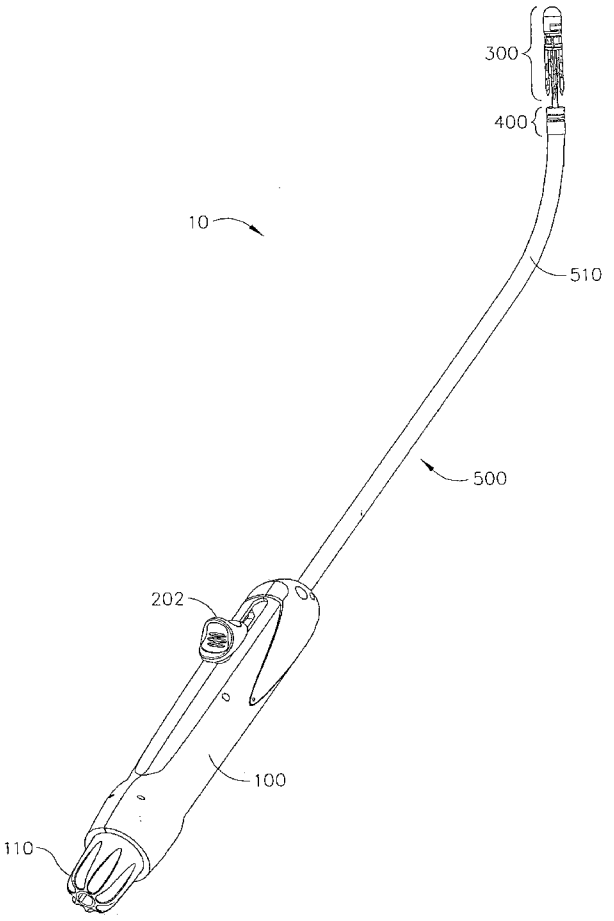
Publication Classification

(51) **Int. Cl.**[7] **A61B 17/08**

(52) **U.S. Cl.** **606/153**

(57) ABSTRACT

The disclosed device can hold, or effect relative longitudinal movement between, two members of a medical instrument, such as an instrument used for fastening two hollow organs together. The device may comprise a handle member having a longitudinal guide defining a line of travel and a longitudinal groove having a detent catch therein; a longitudinally spring-biased moving member slidable within the longitudinal guide and having pawl receiving slots along a line parallel with the line of travel; and a transversely and rotationally spring-biased driving trigger member comprising a pawl proximate to the moving member and adapted to engage the pawl receiving slots when aligned therewith, and a fulcrum member movable within the groove and adapted to be releasably captured by the detent, the driving trigger member being rotatable about the fulcrum member to cause the pawl to engage or disengage the pawl receiving slots.



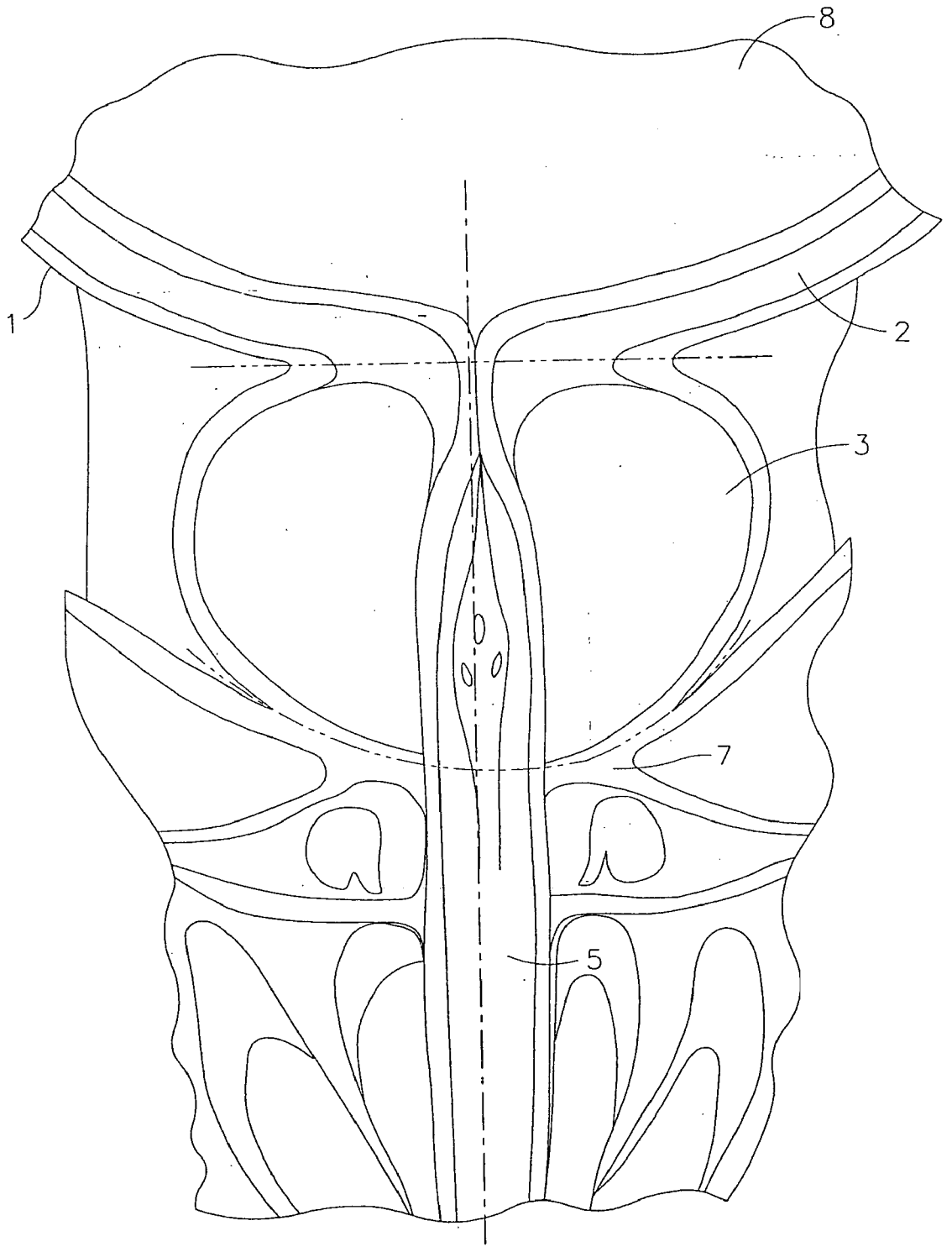


FIG. 1

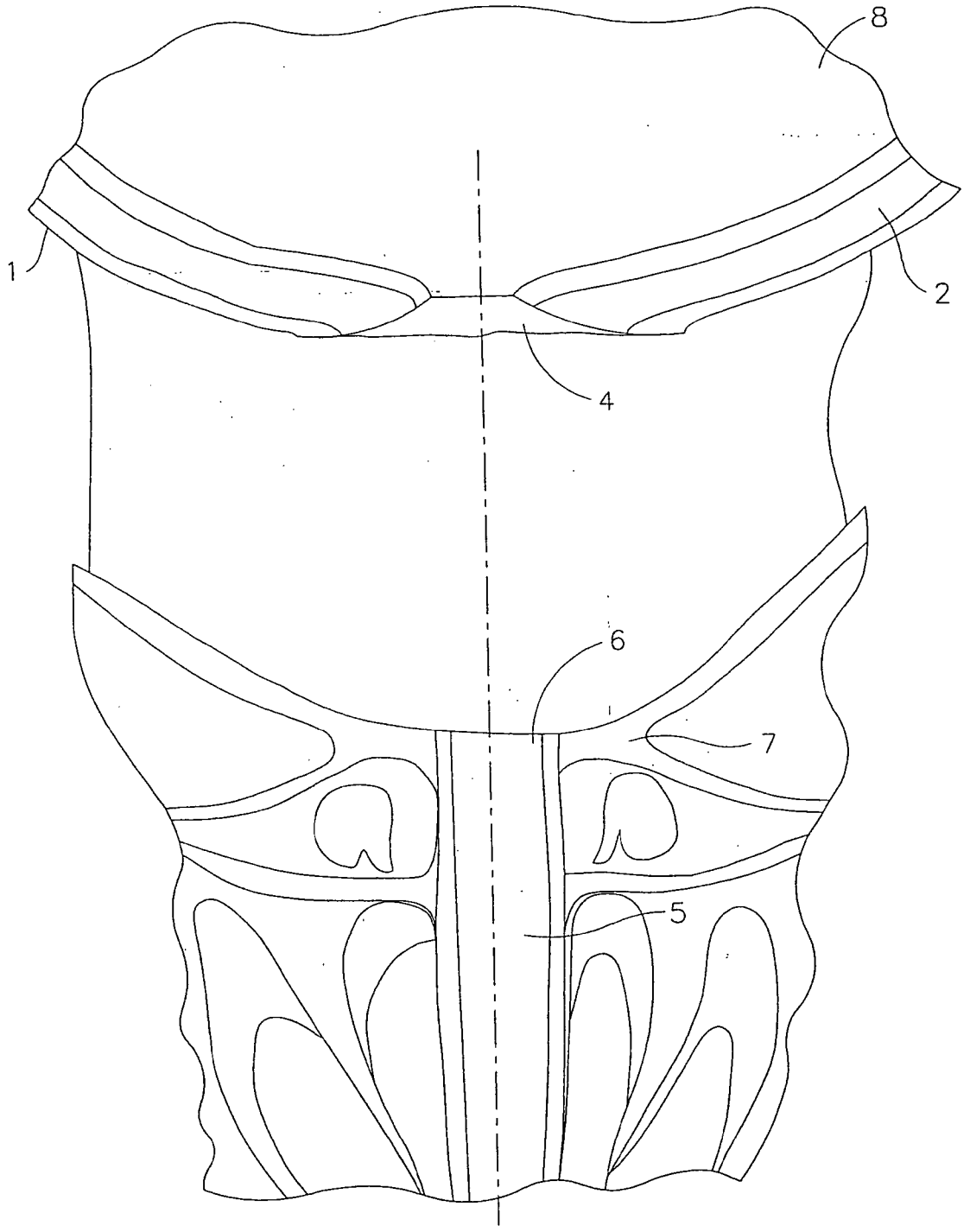
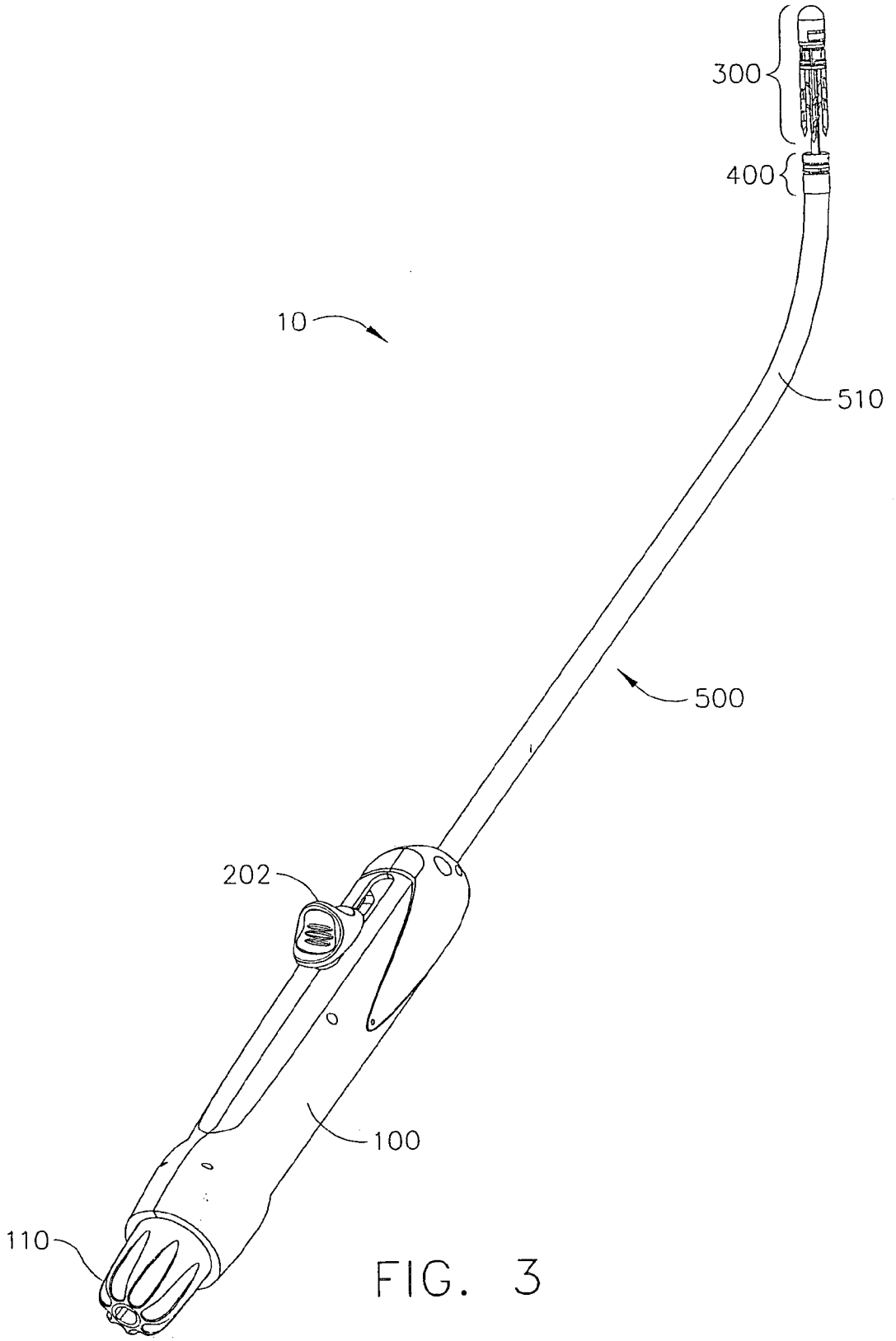


FIG. 2



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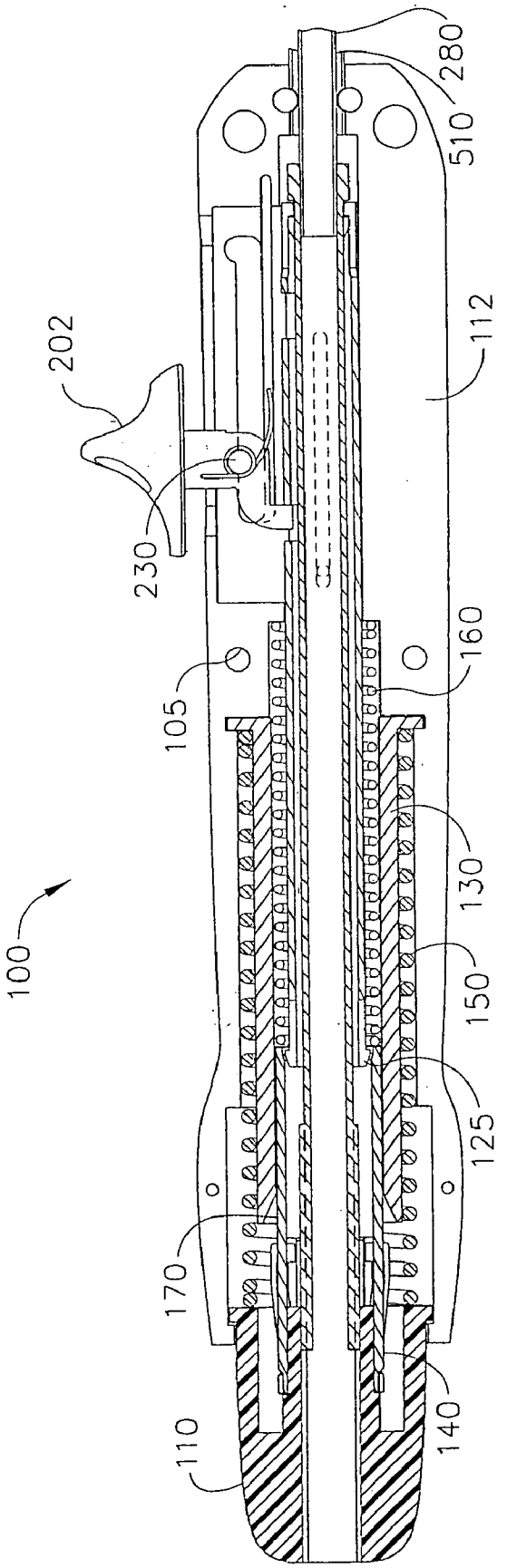

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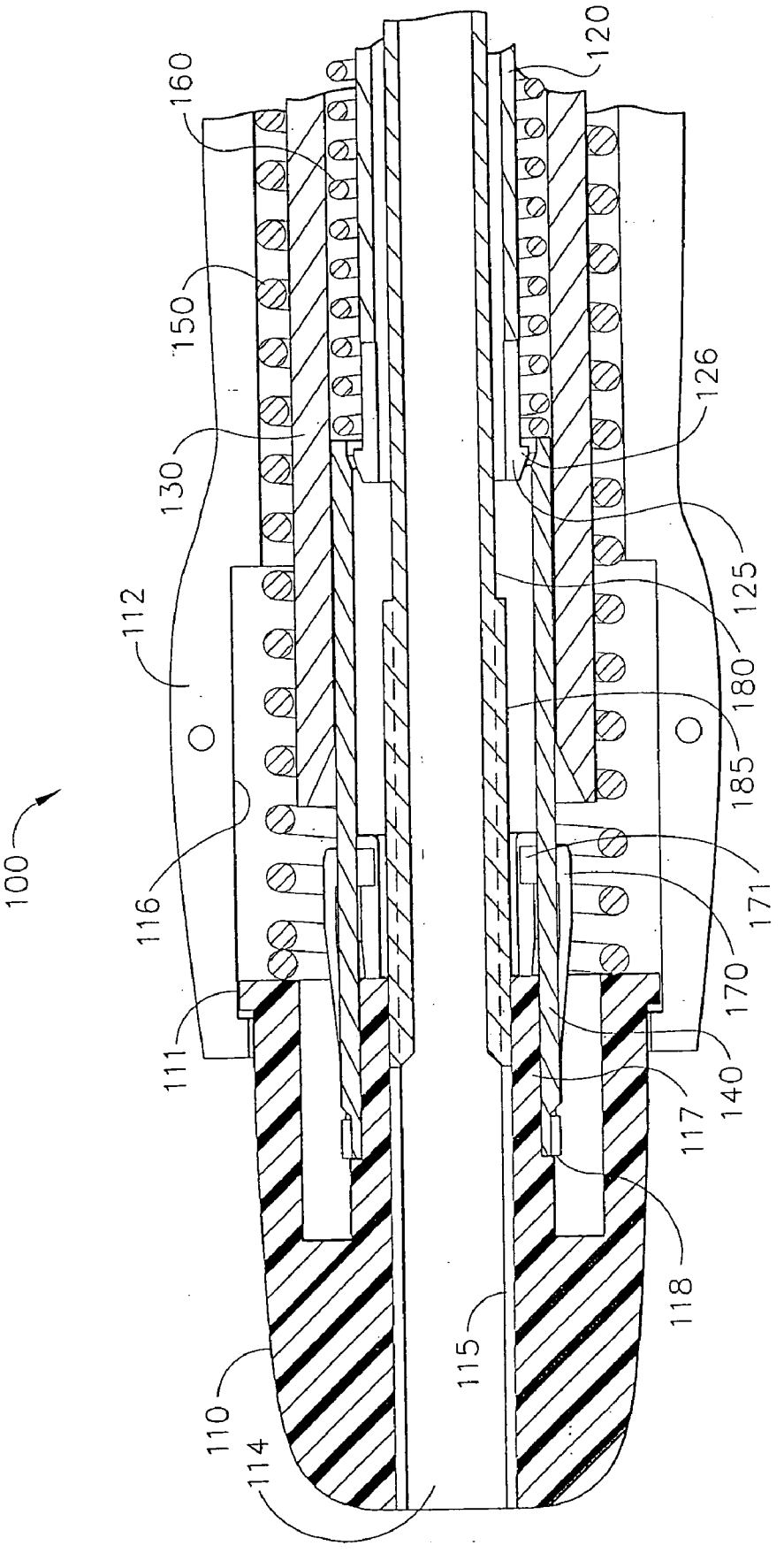
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FIG. 5

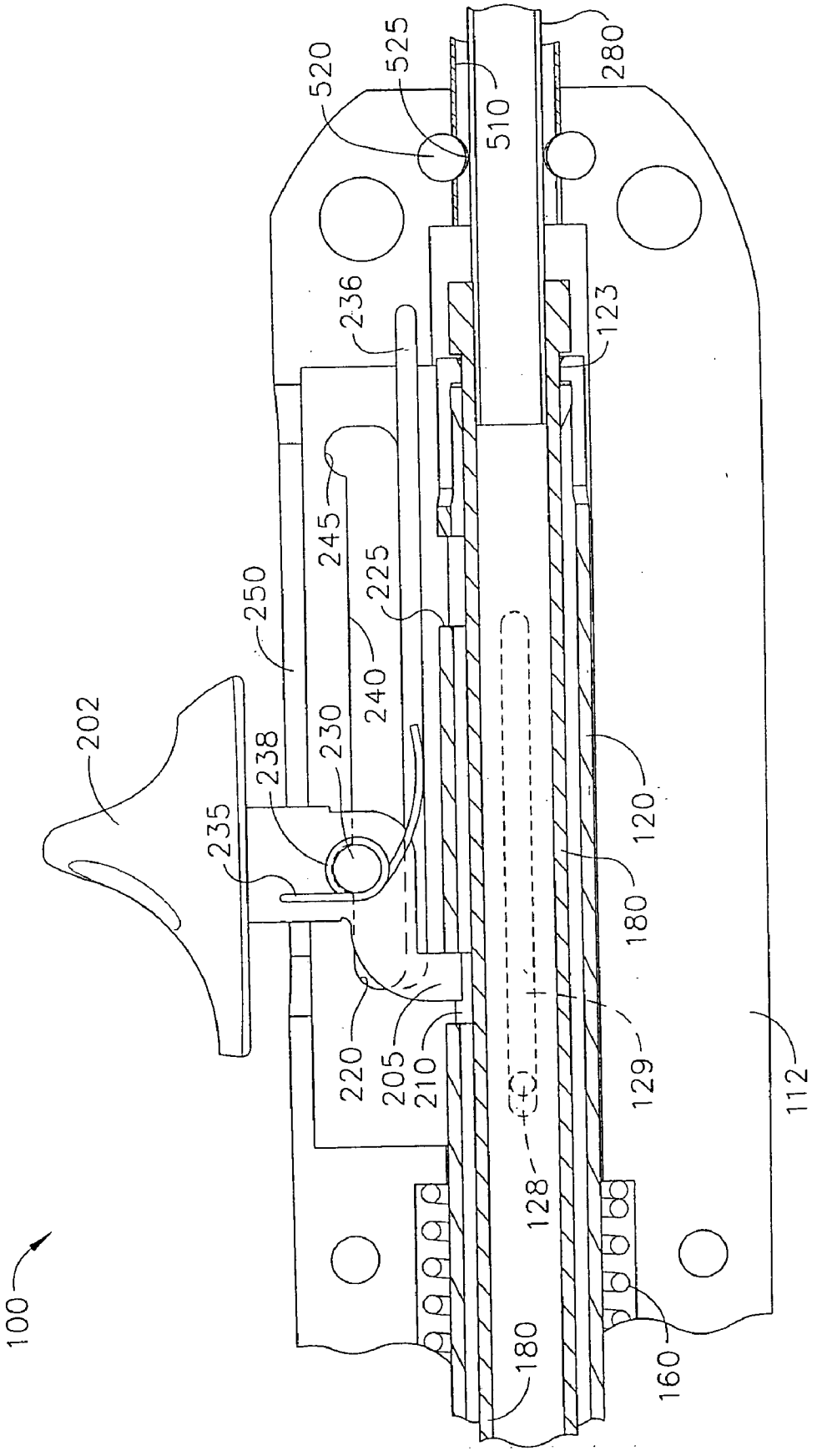
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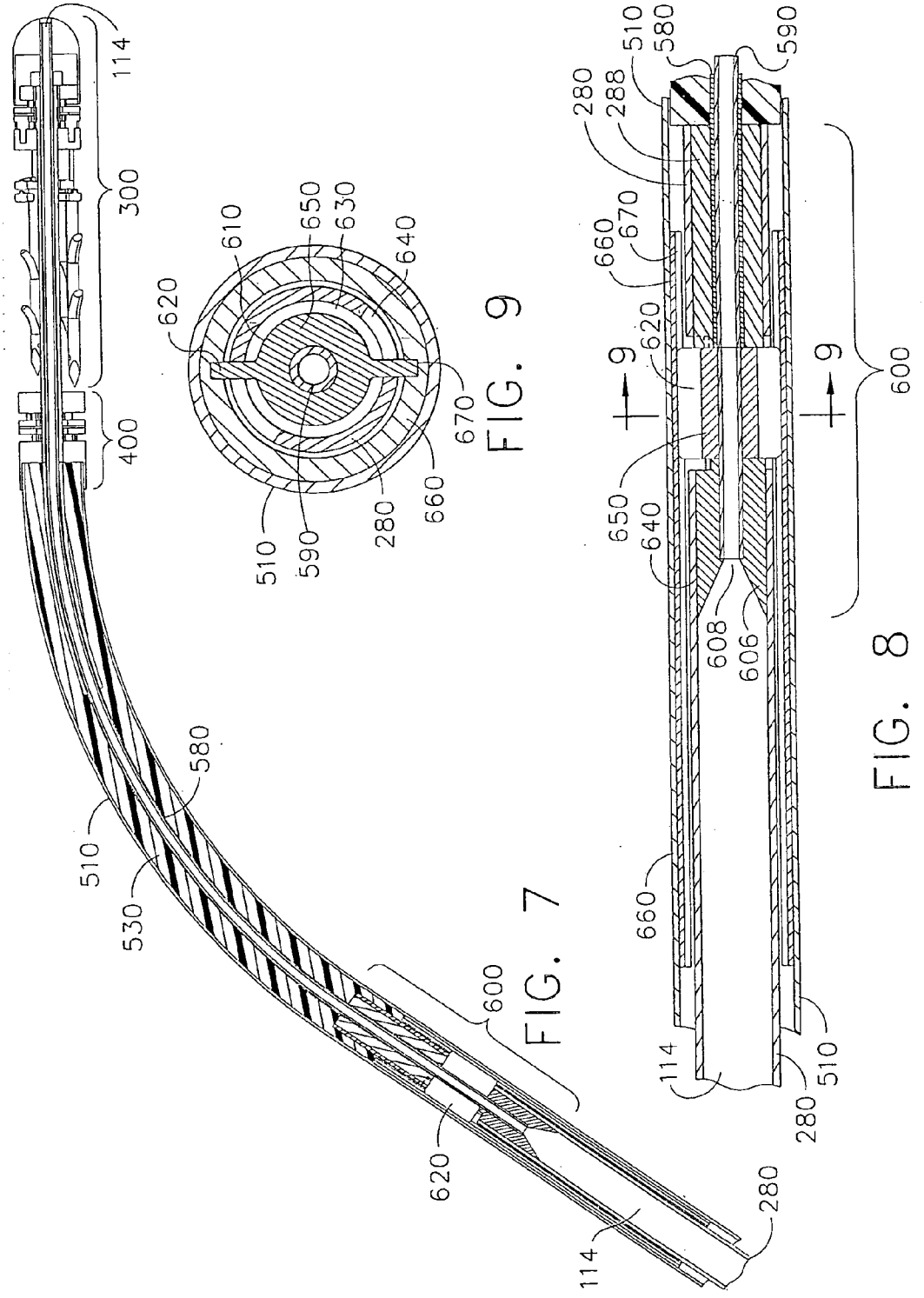
FIG. 6



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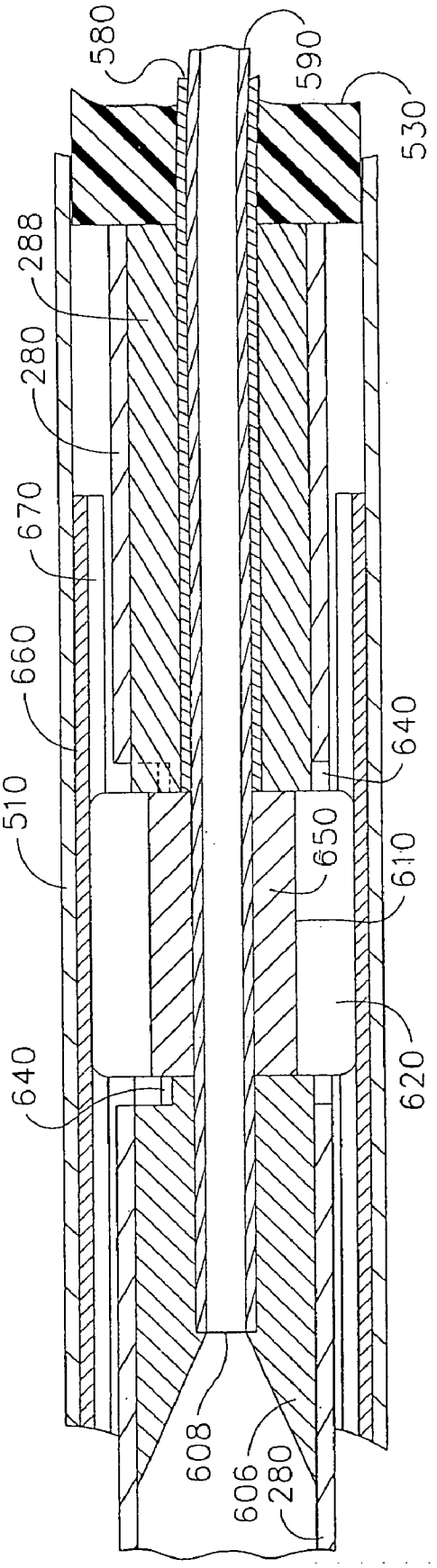

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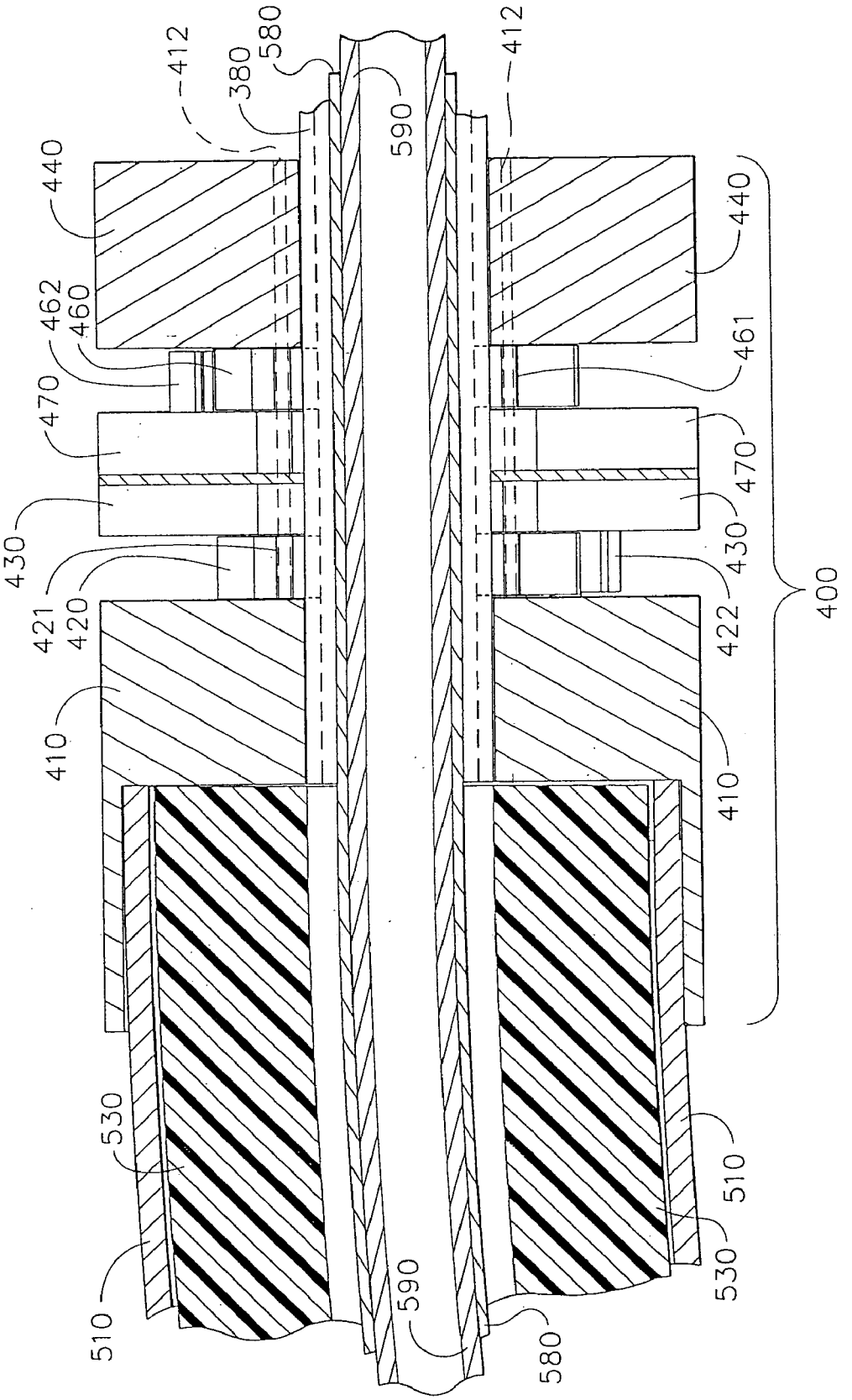
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FIG. 11

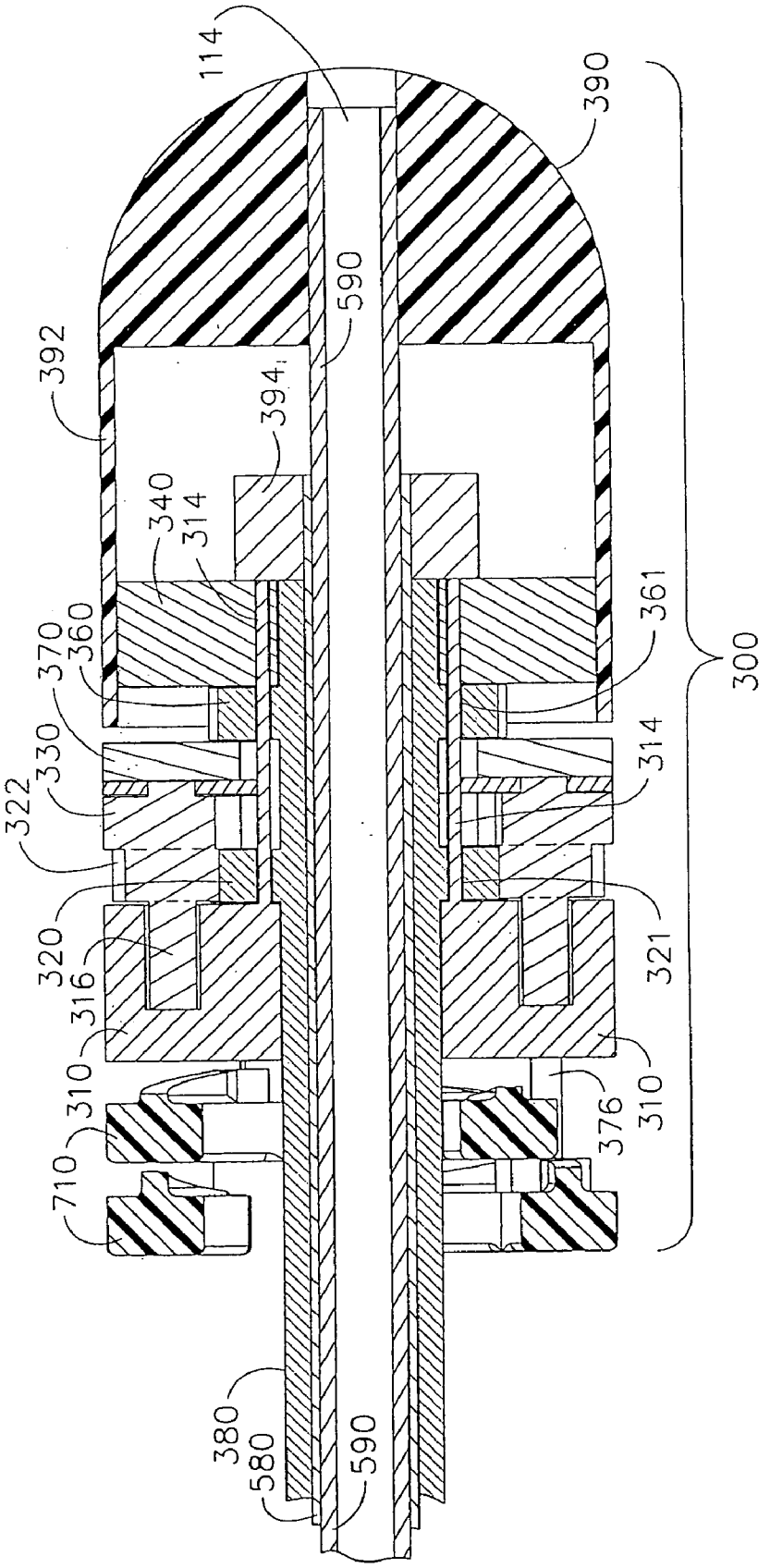
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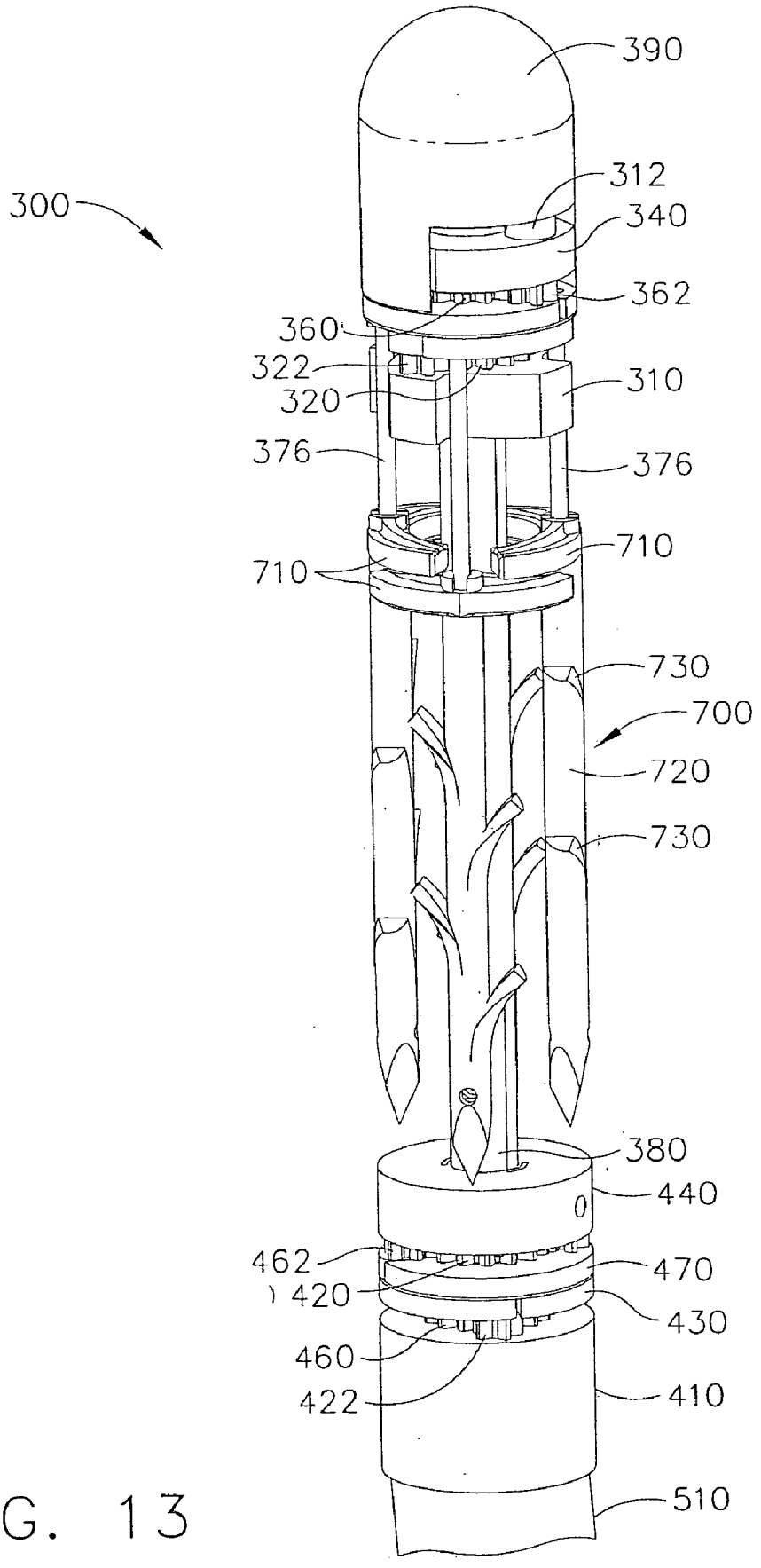
FIG. 12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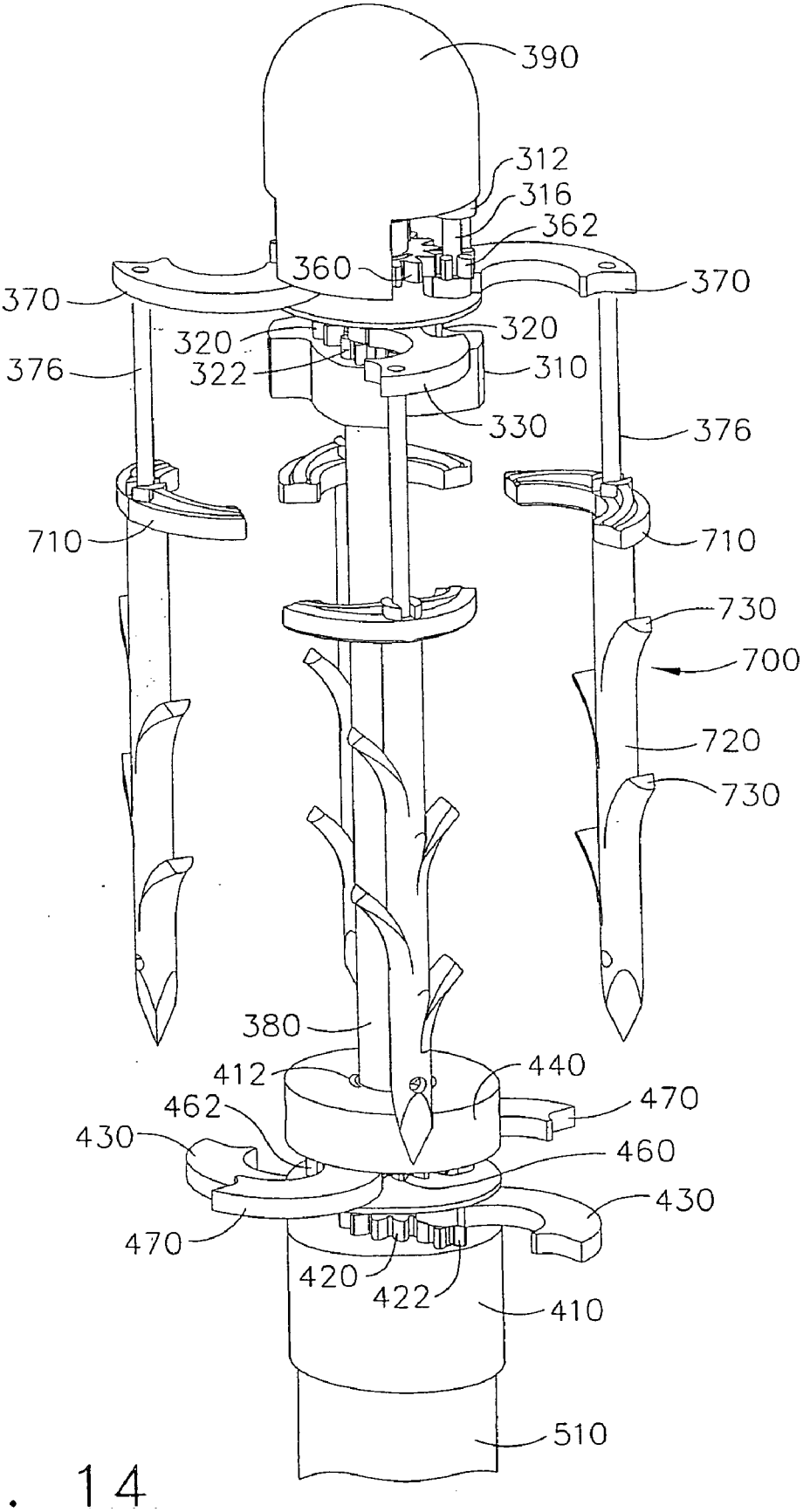
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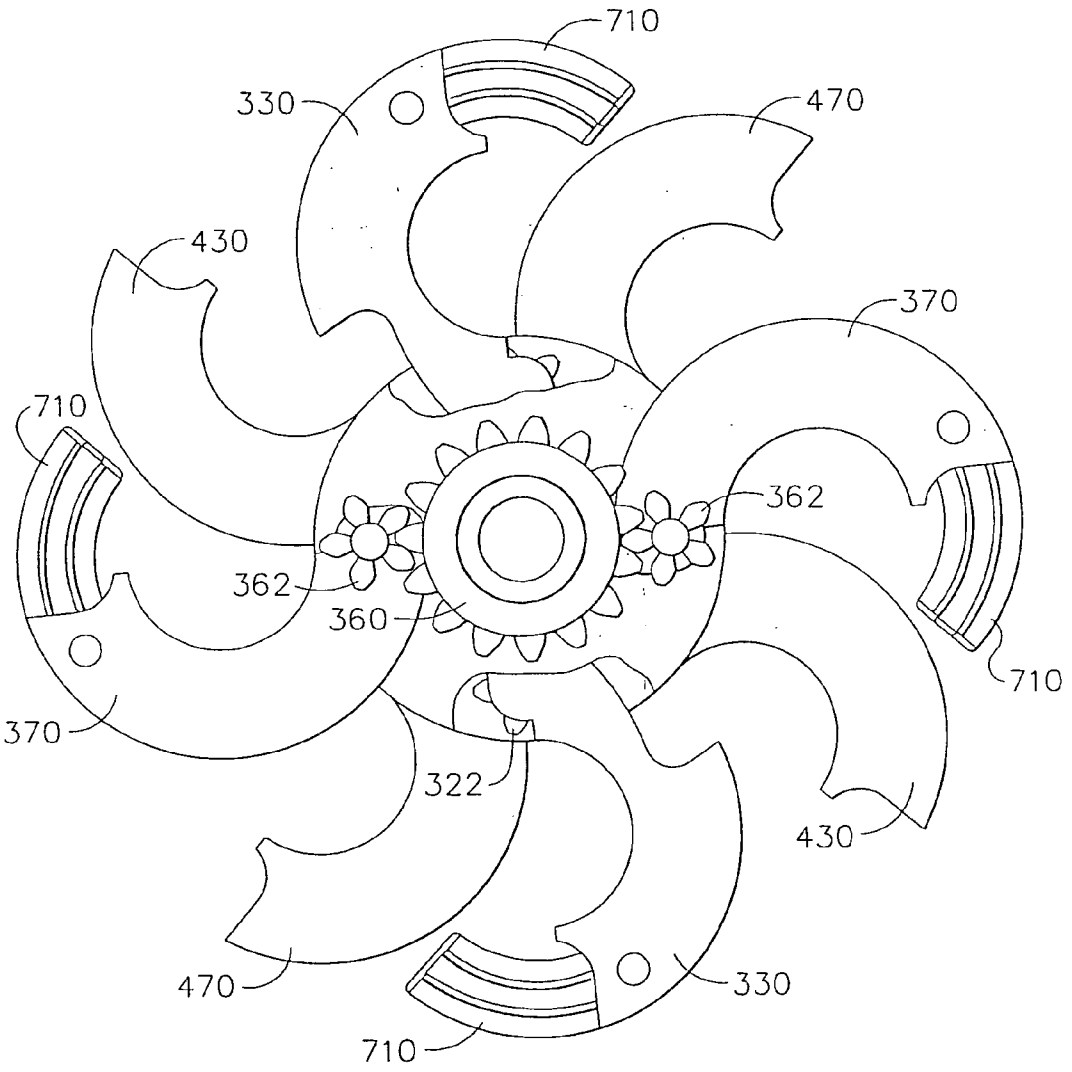
FIG. 14



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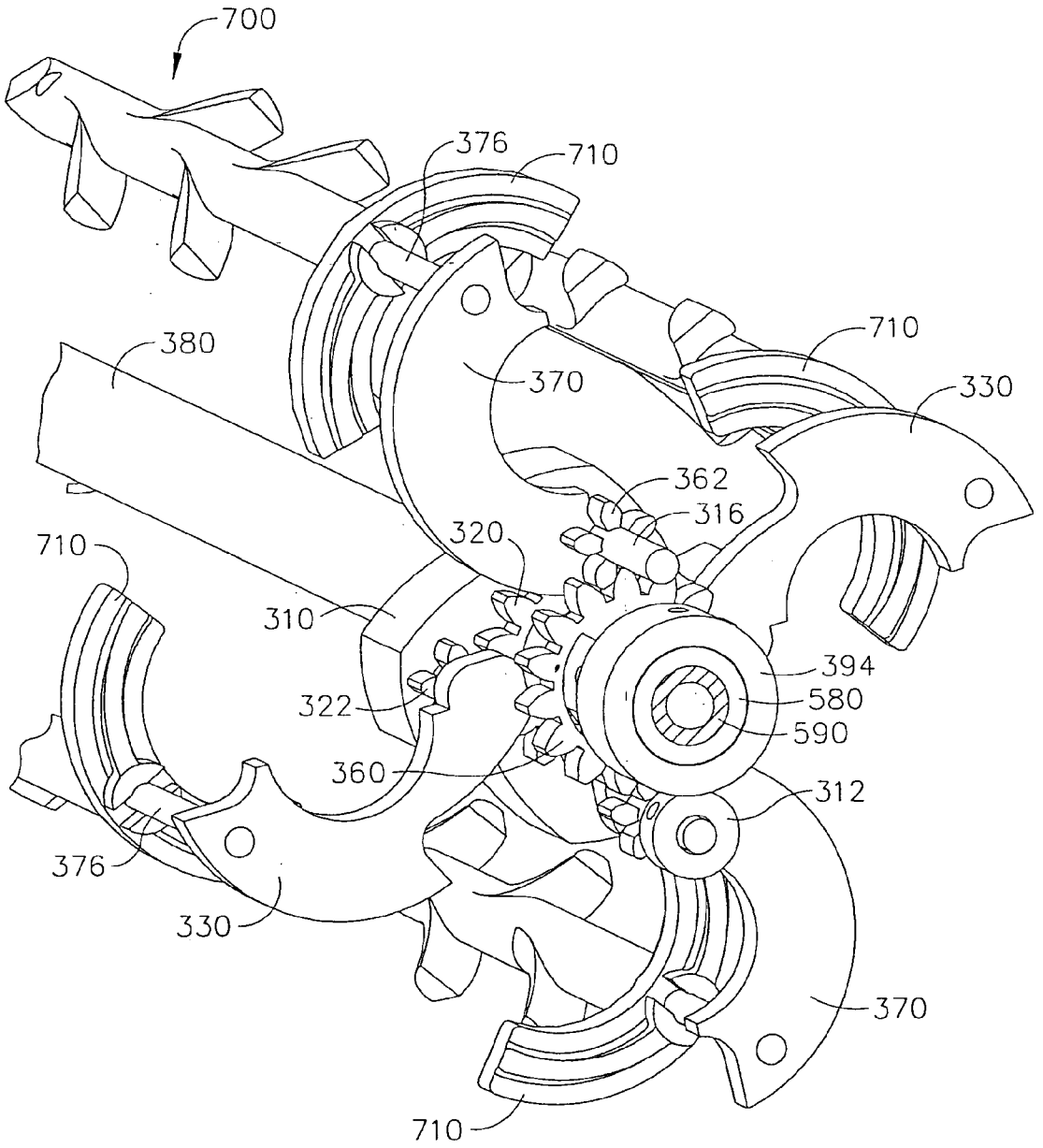
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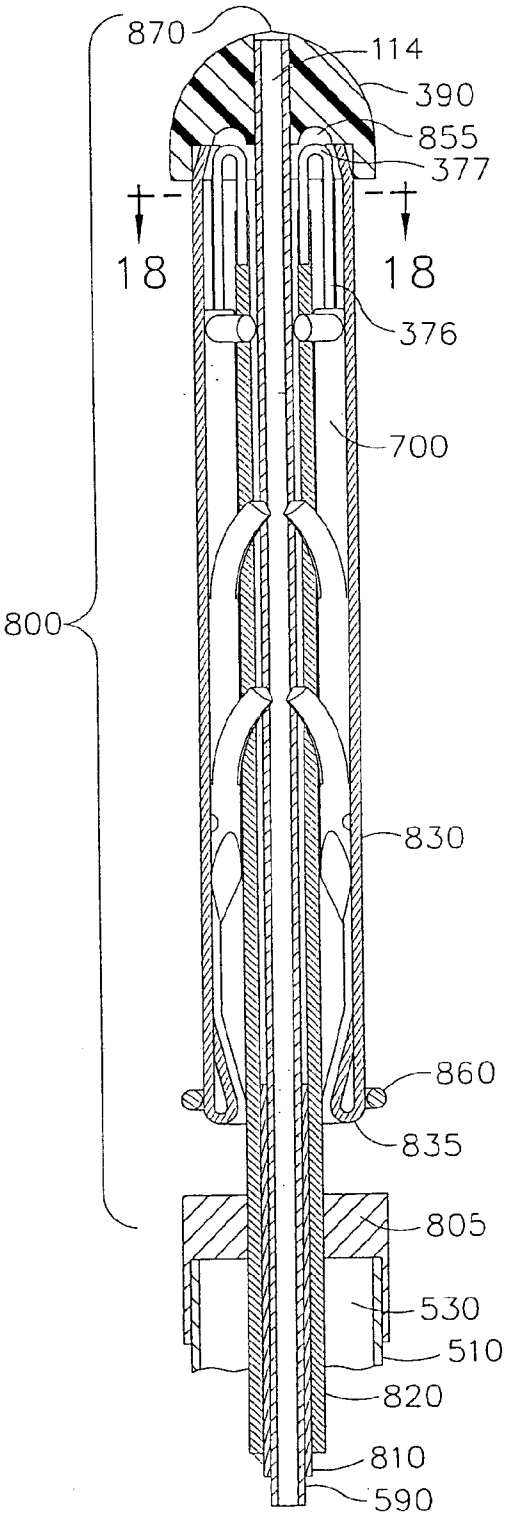
FIG. 16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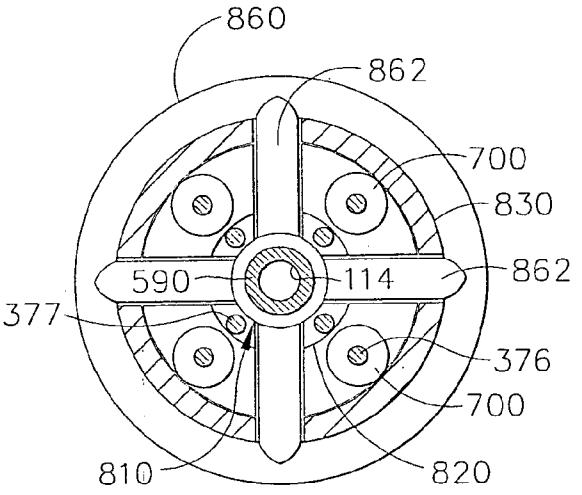
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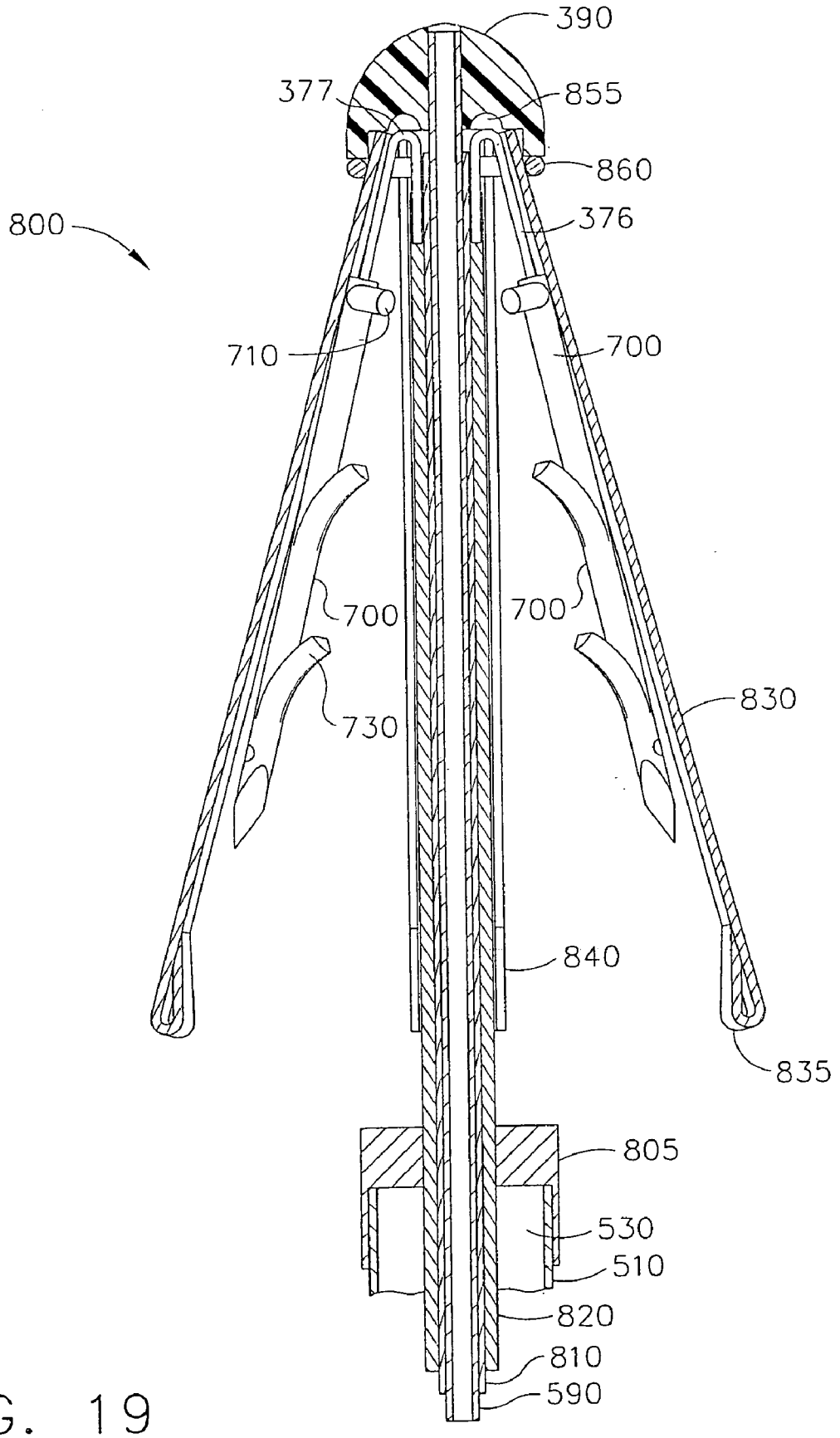
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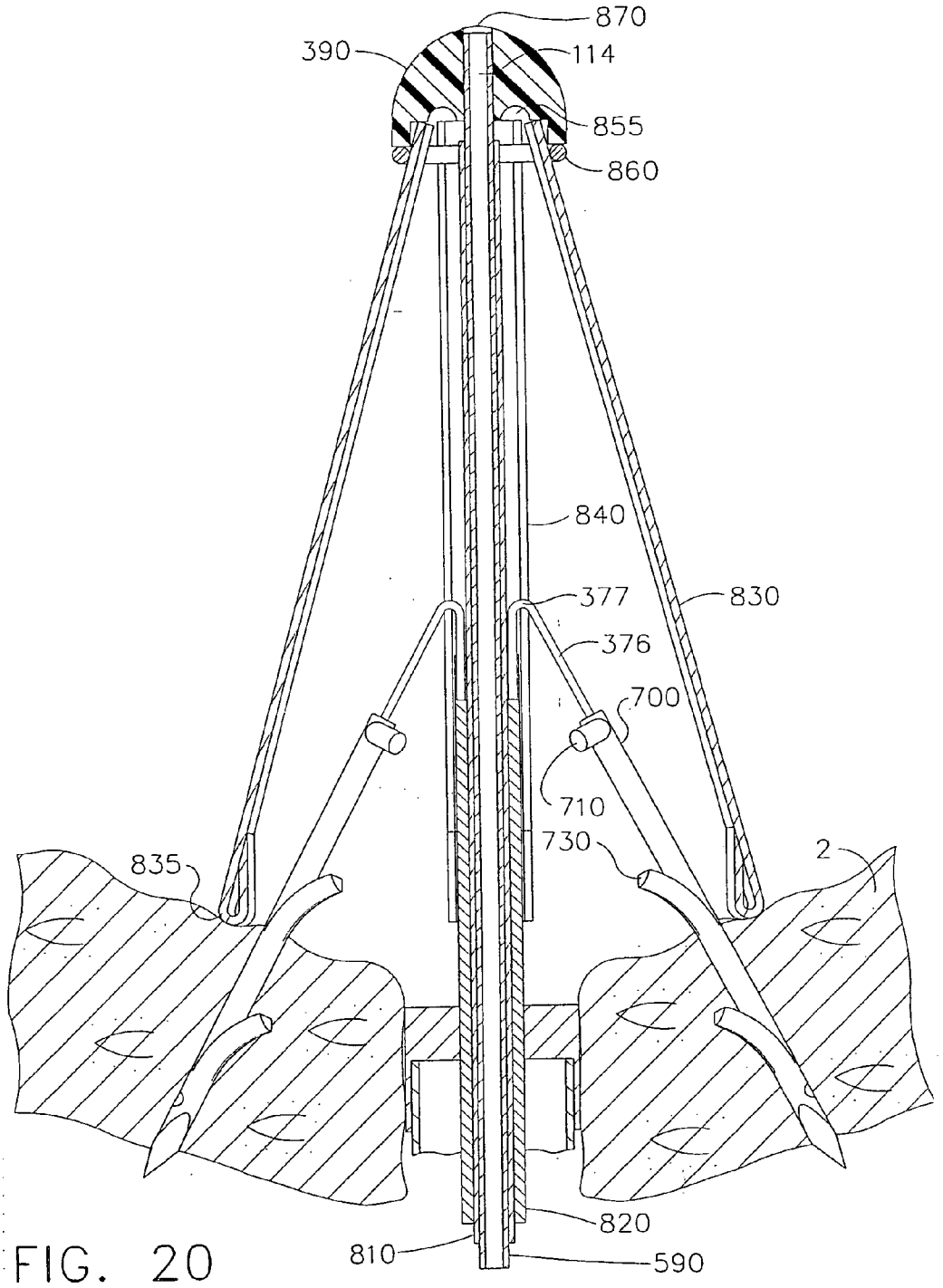
FIG. 19



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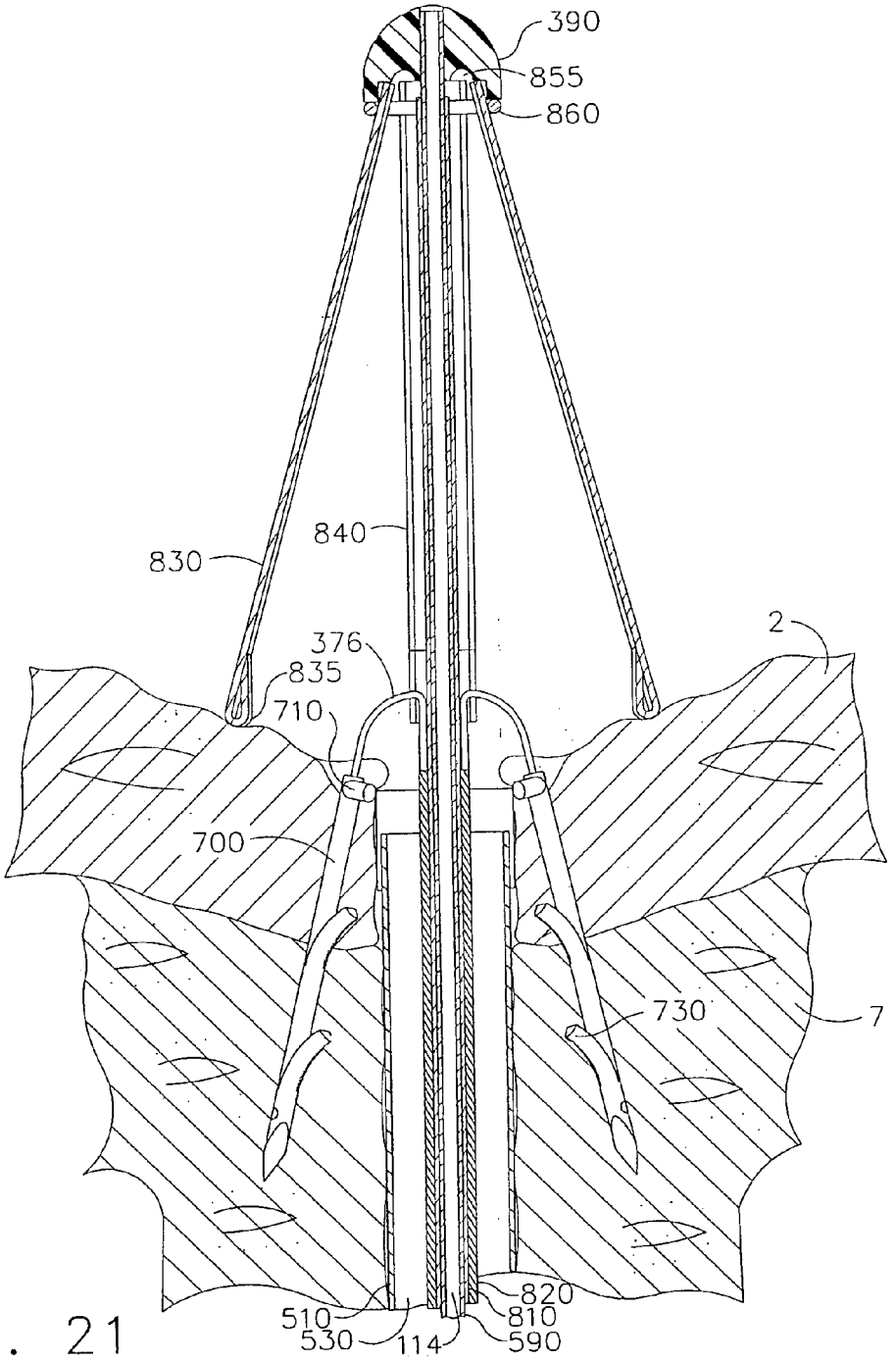
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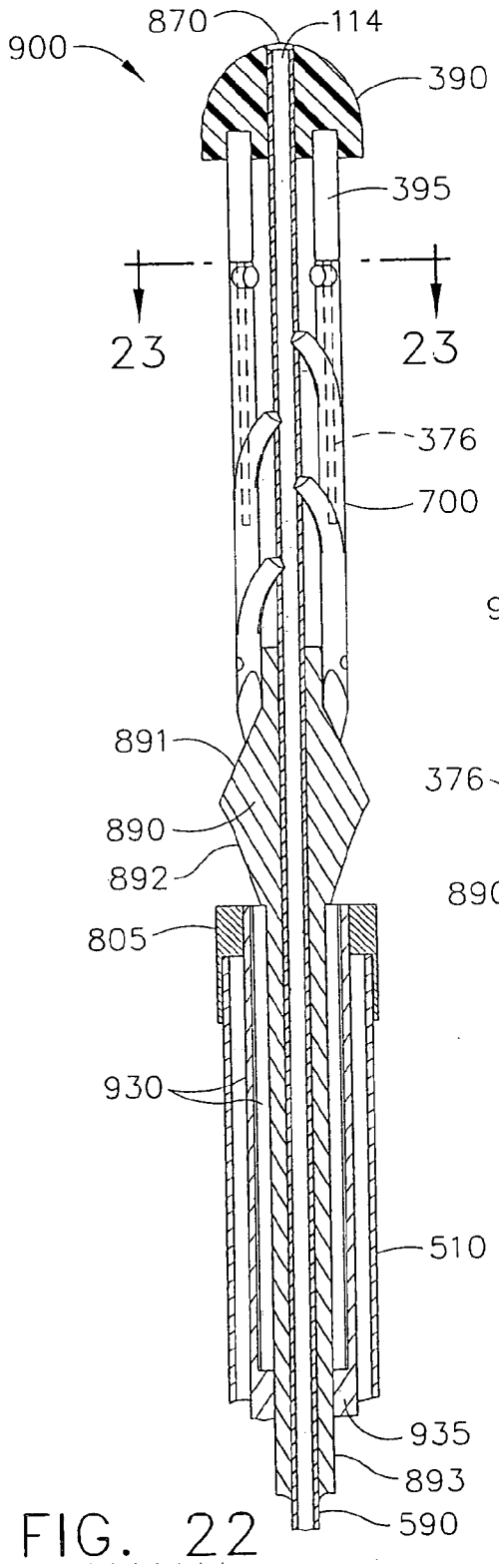
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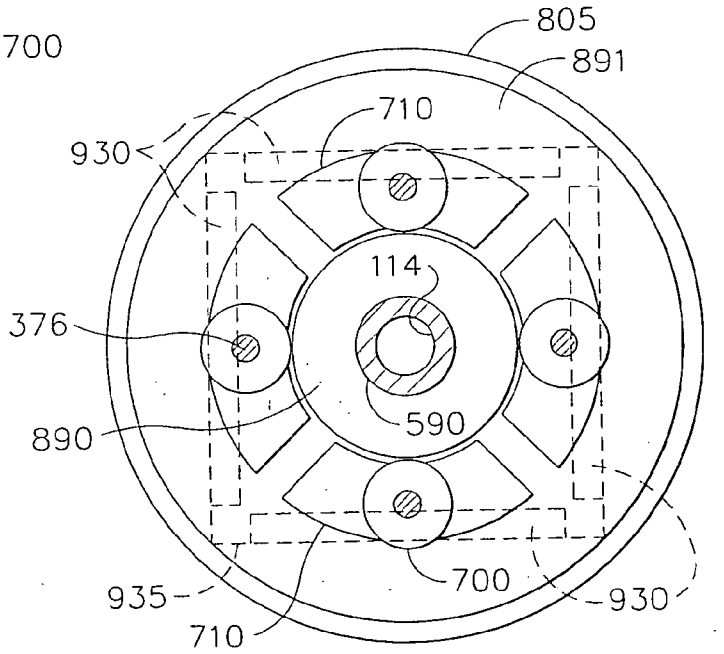
FIG. 22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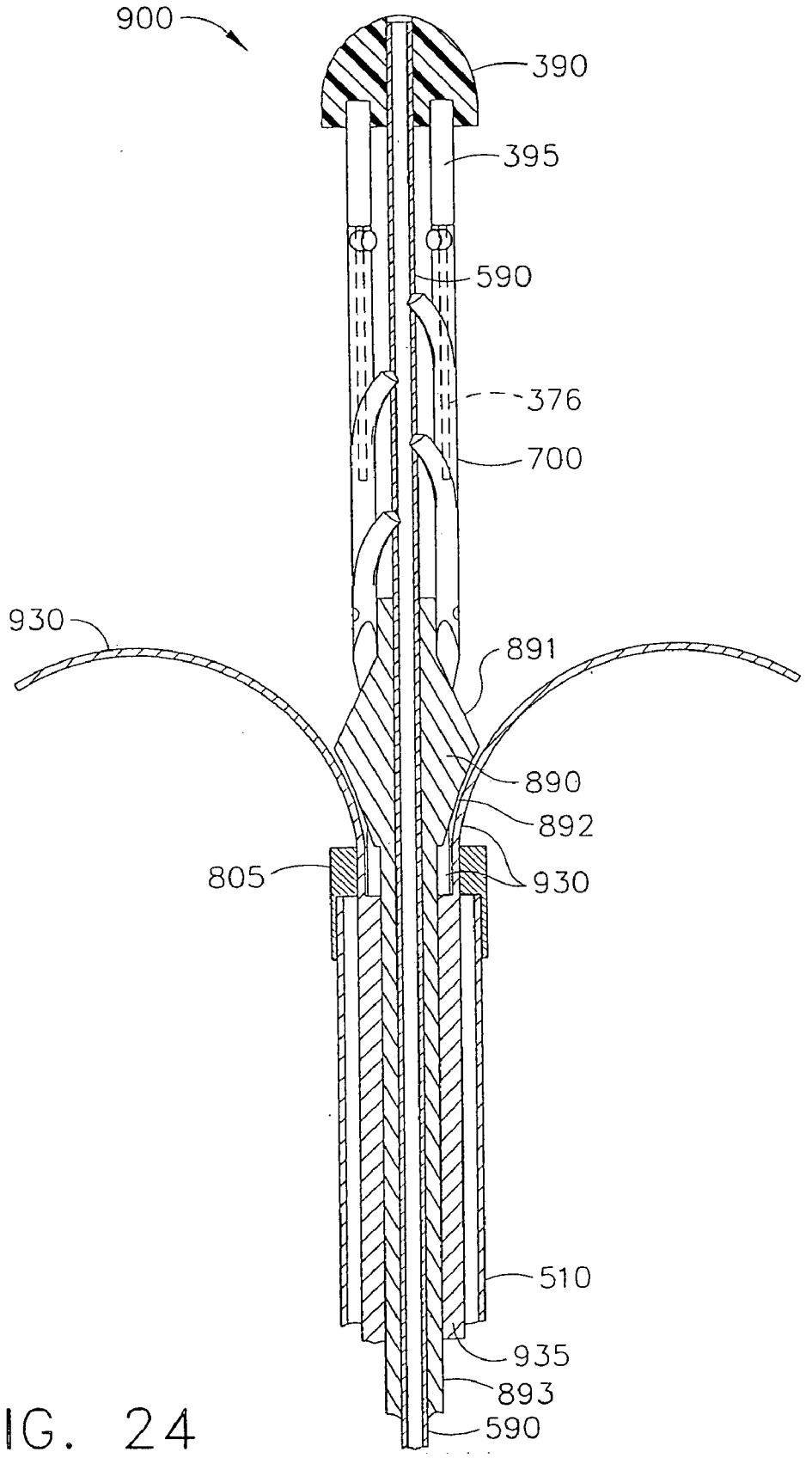

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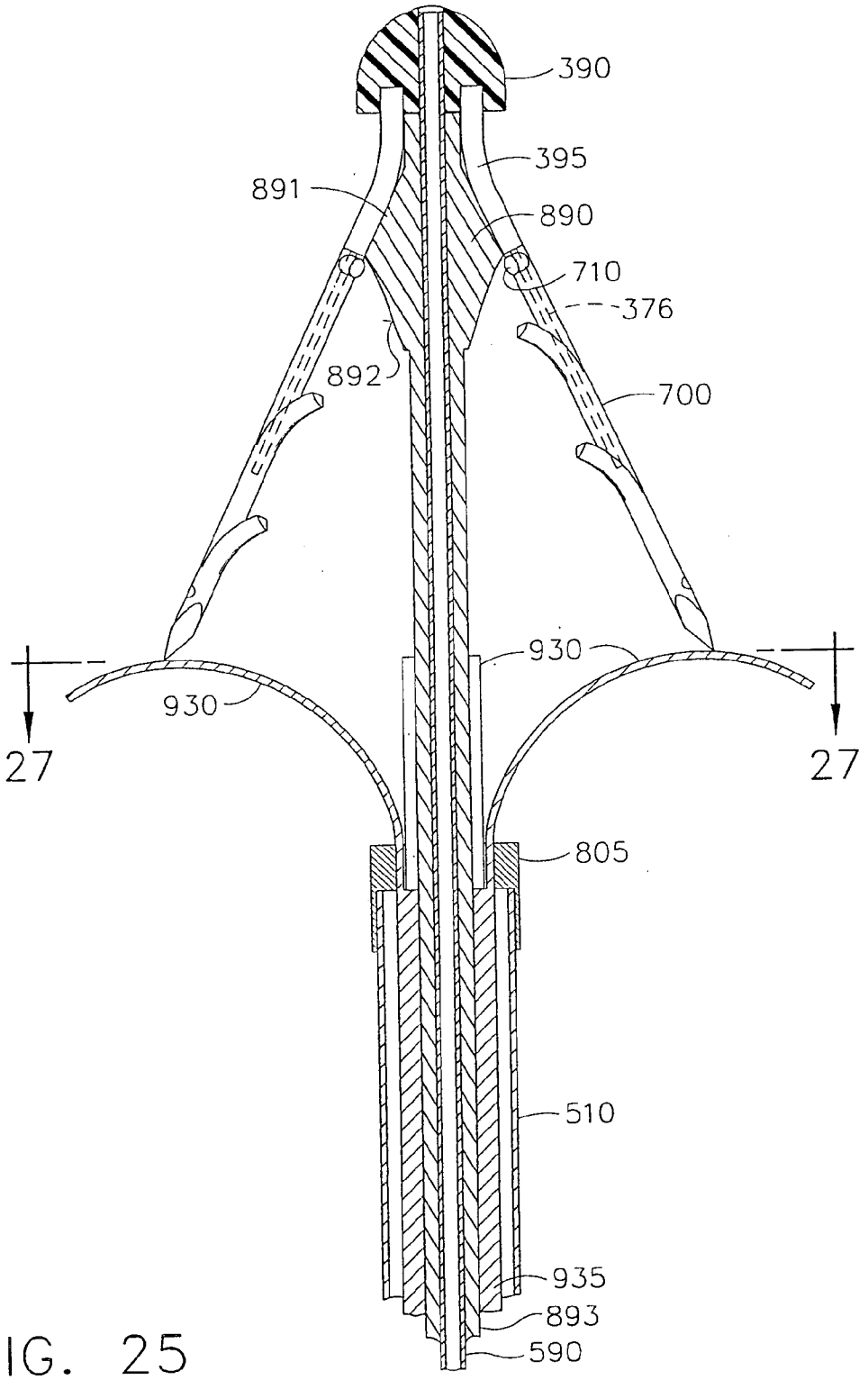

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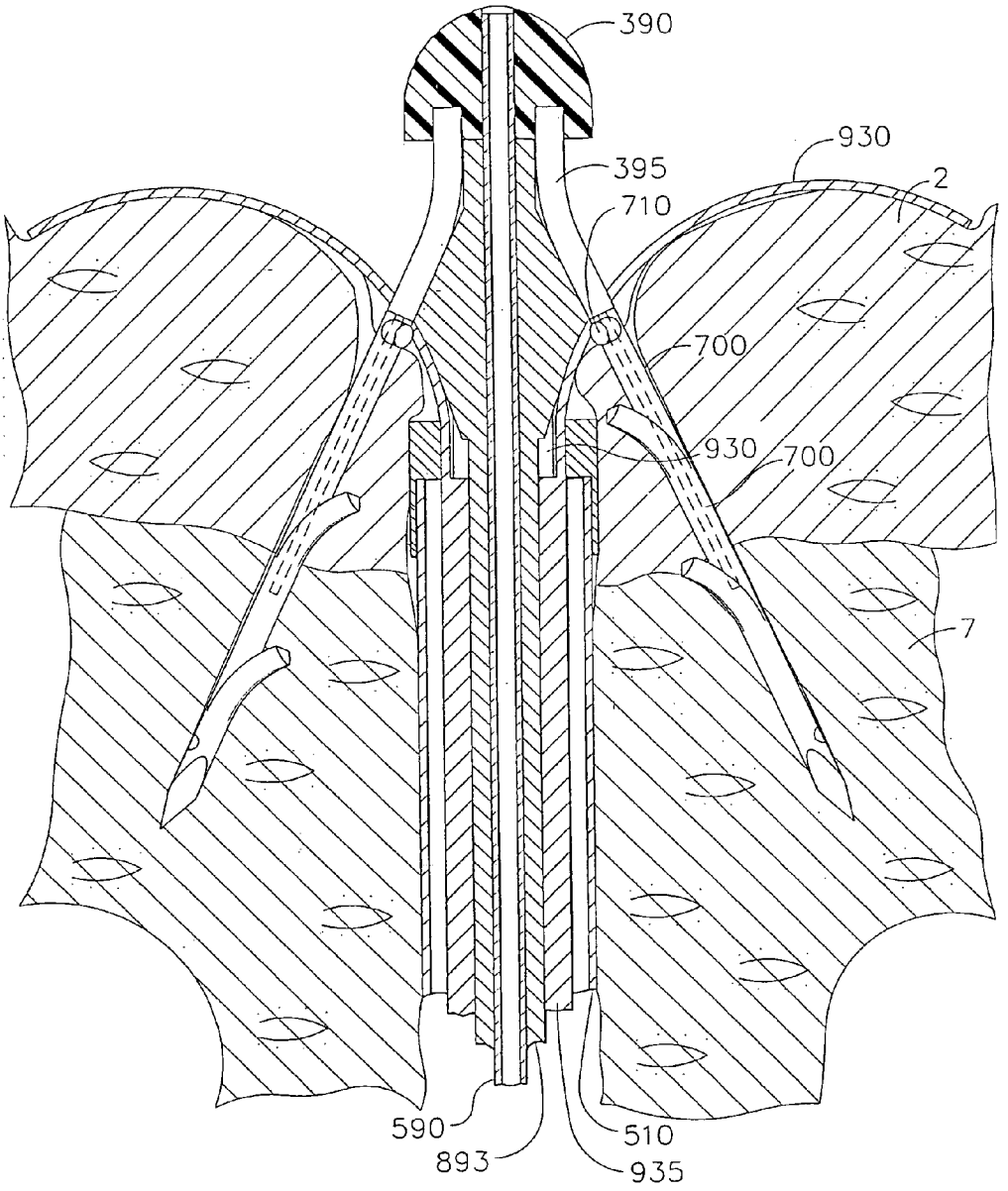

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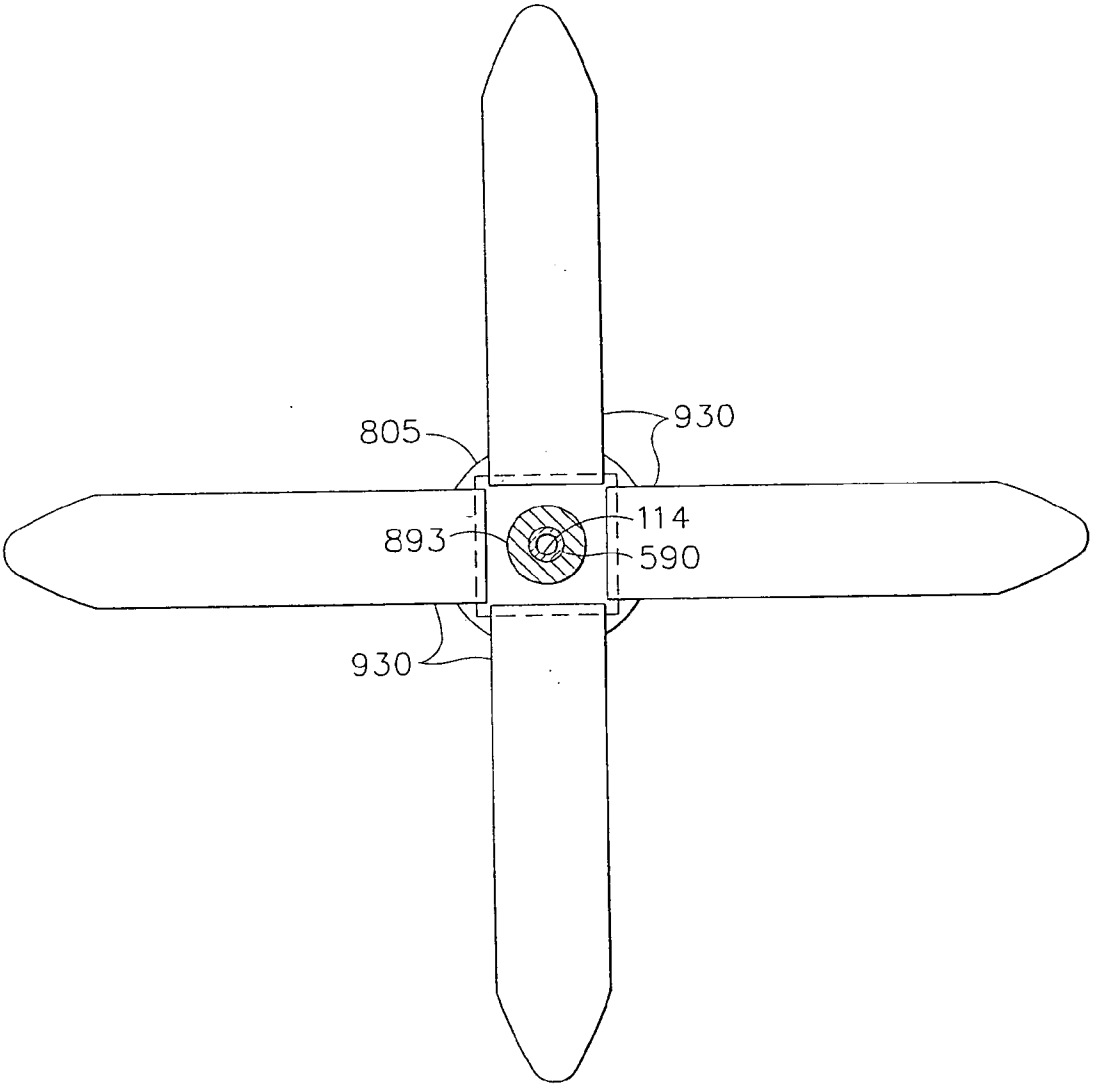

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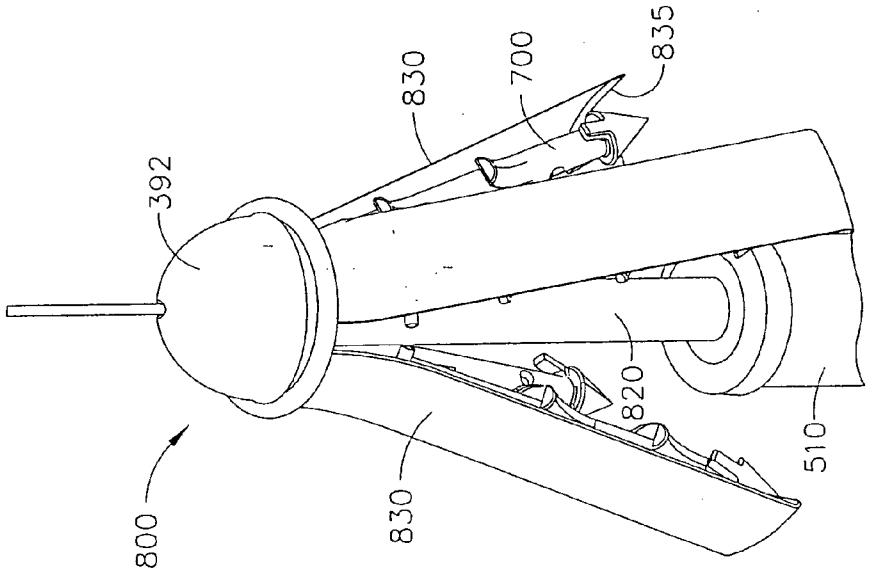

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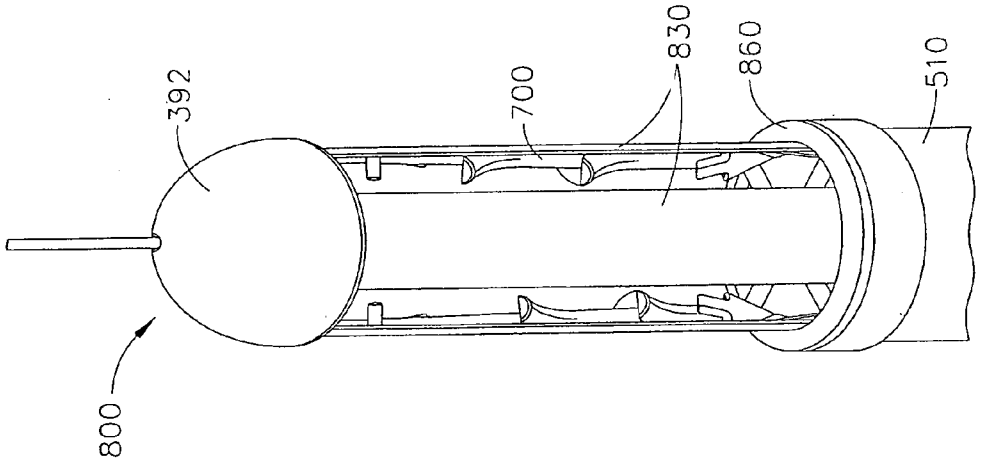

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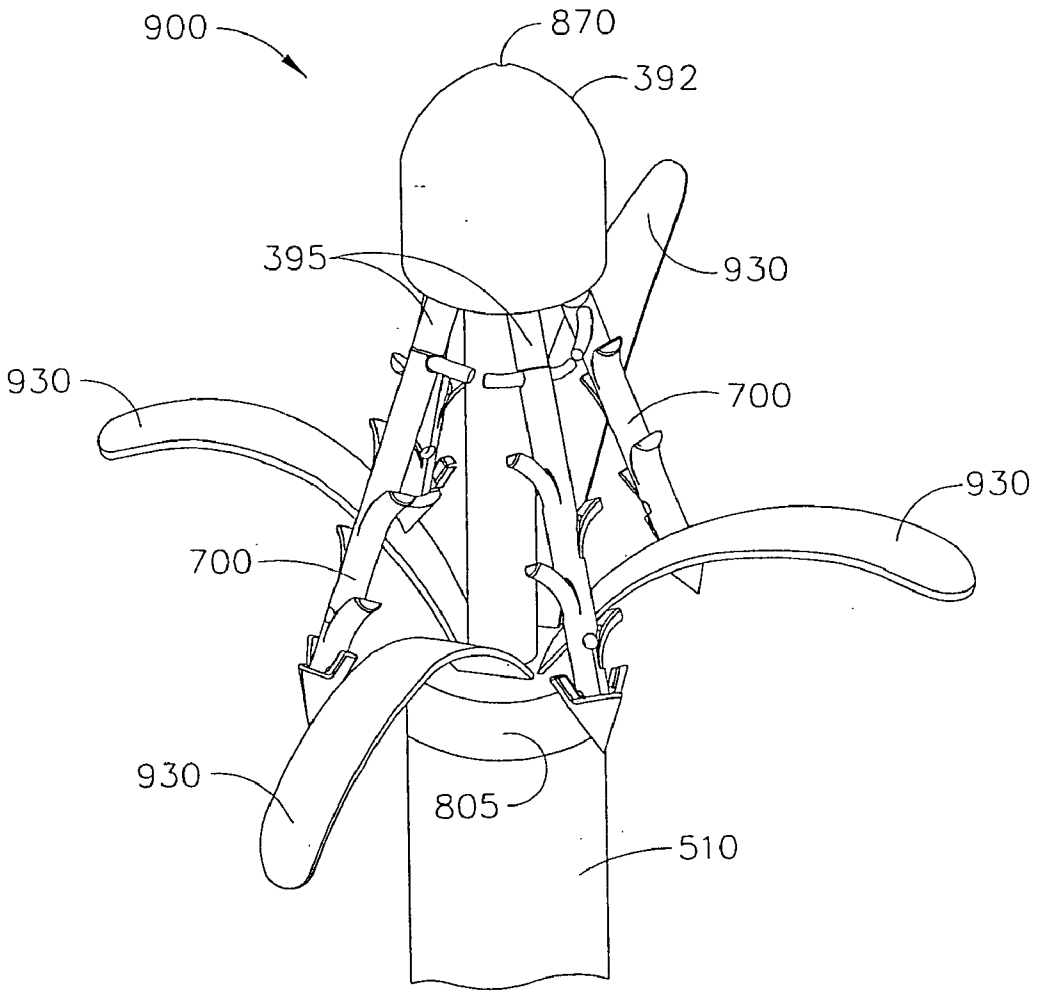

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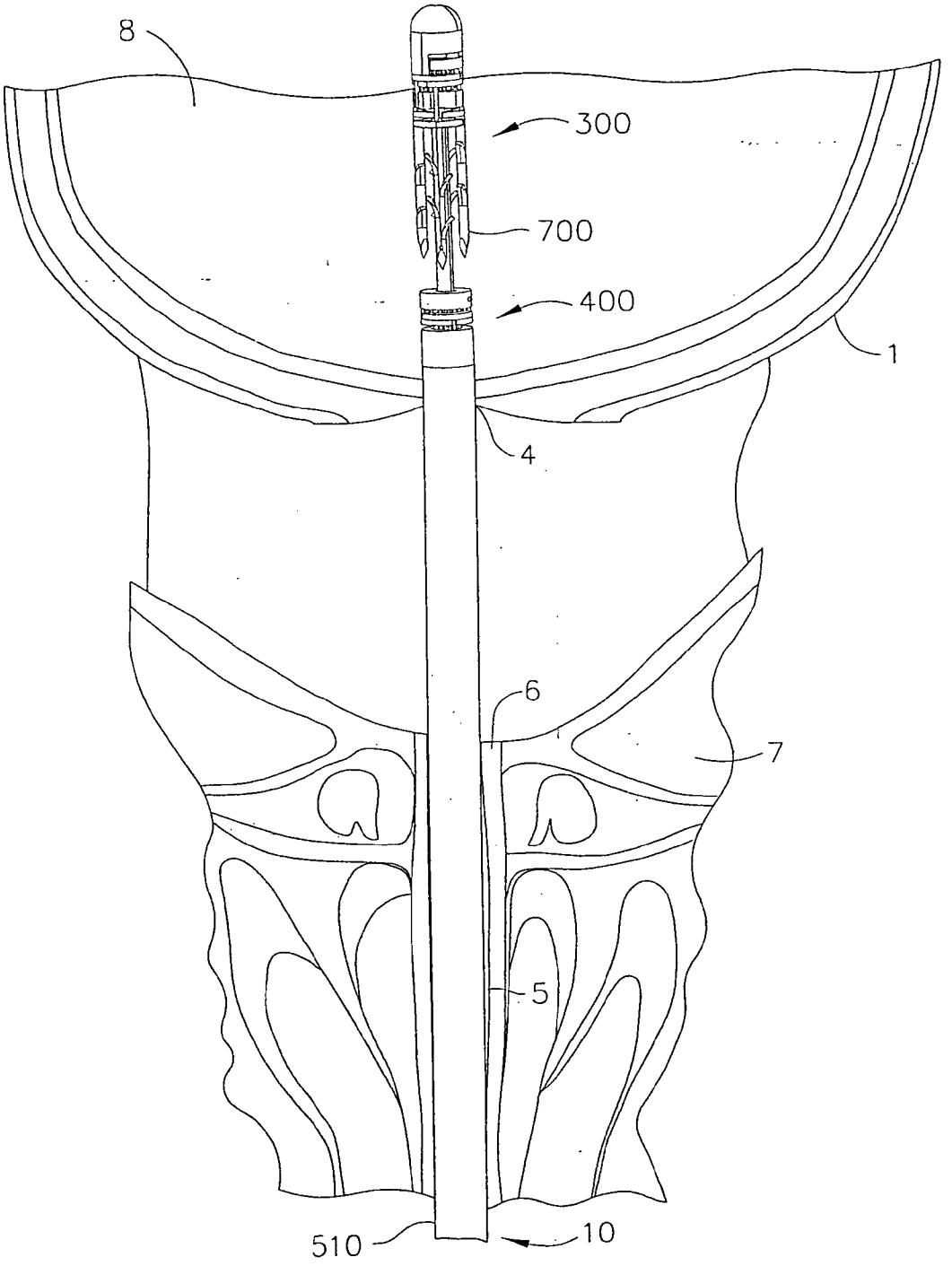

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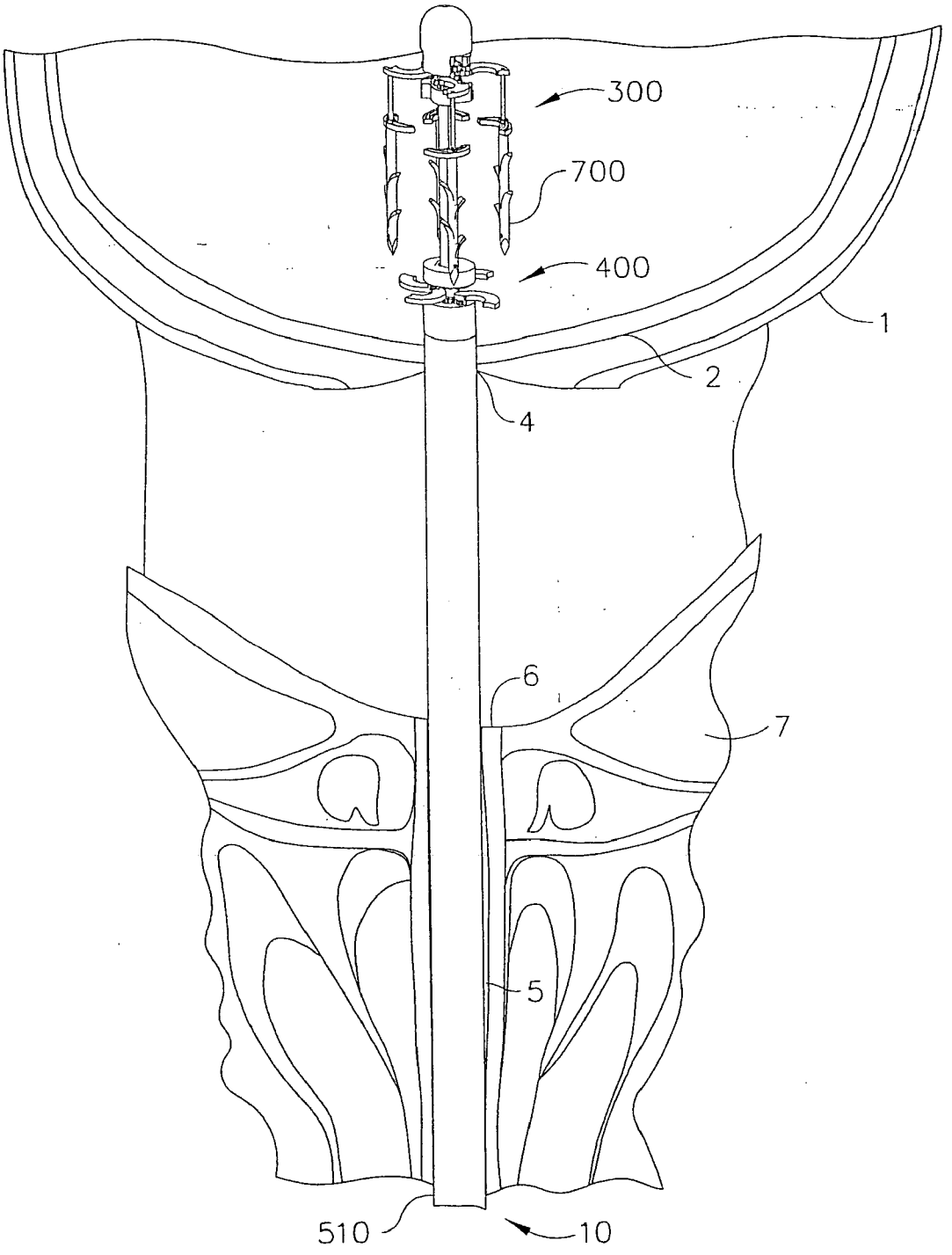

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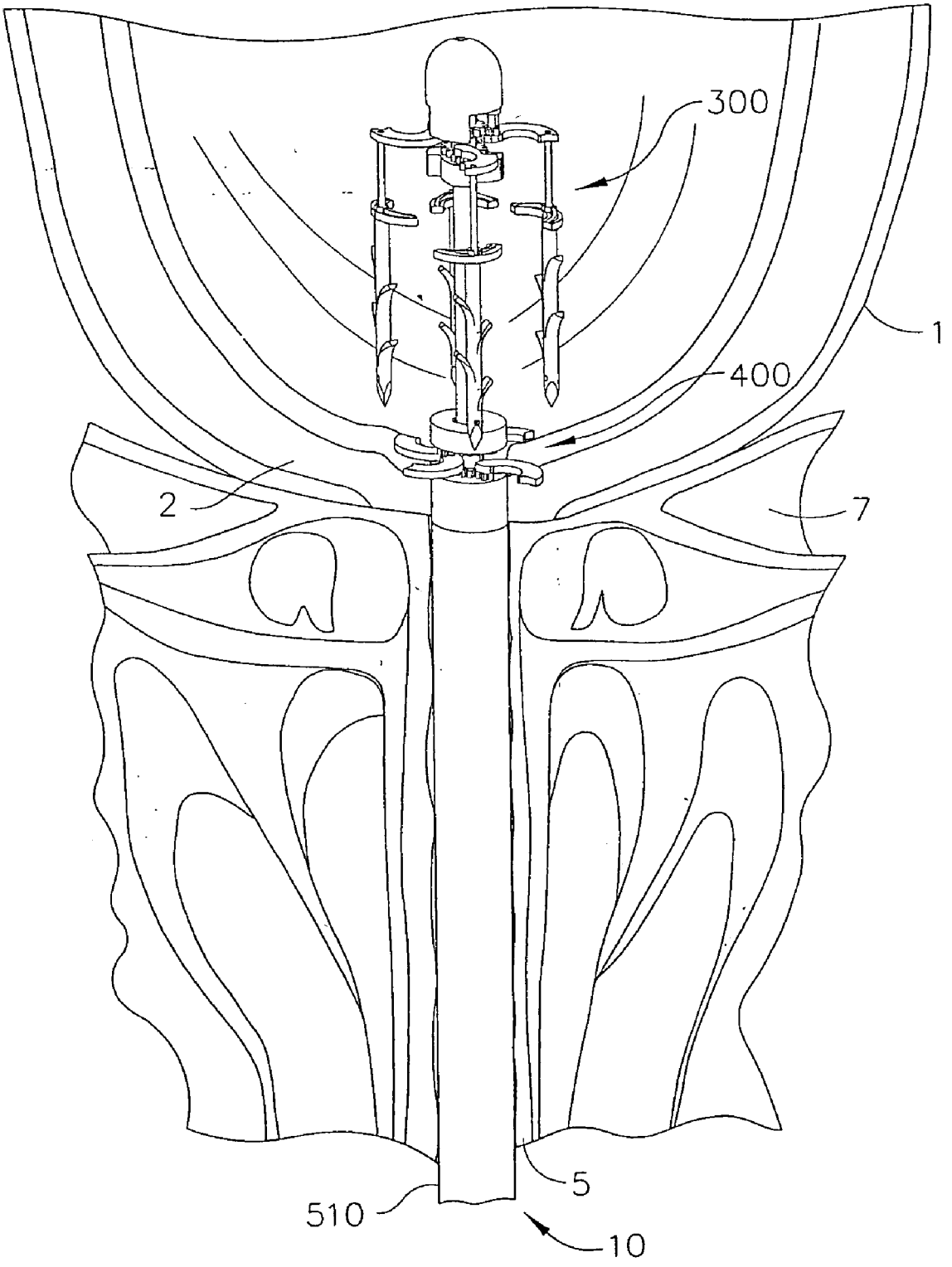

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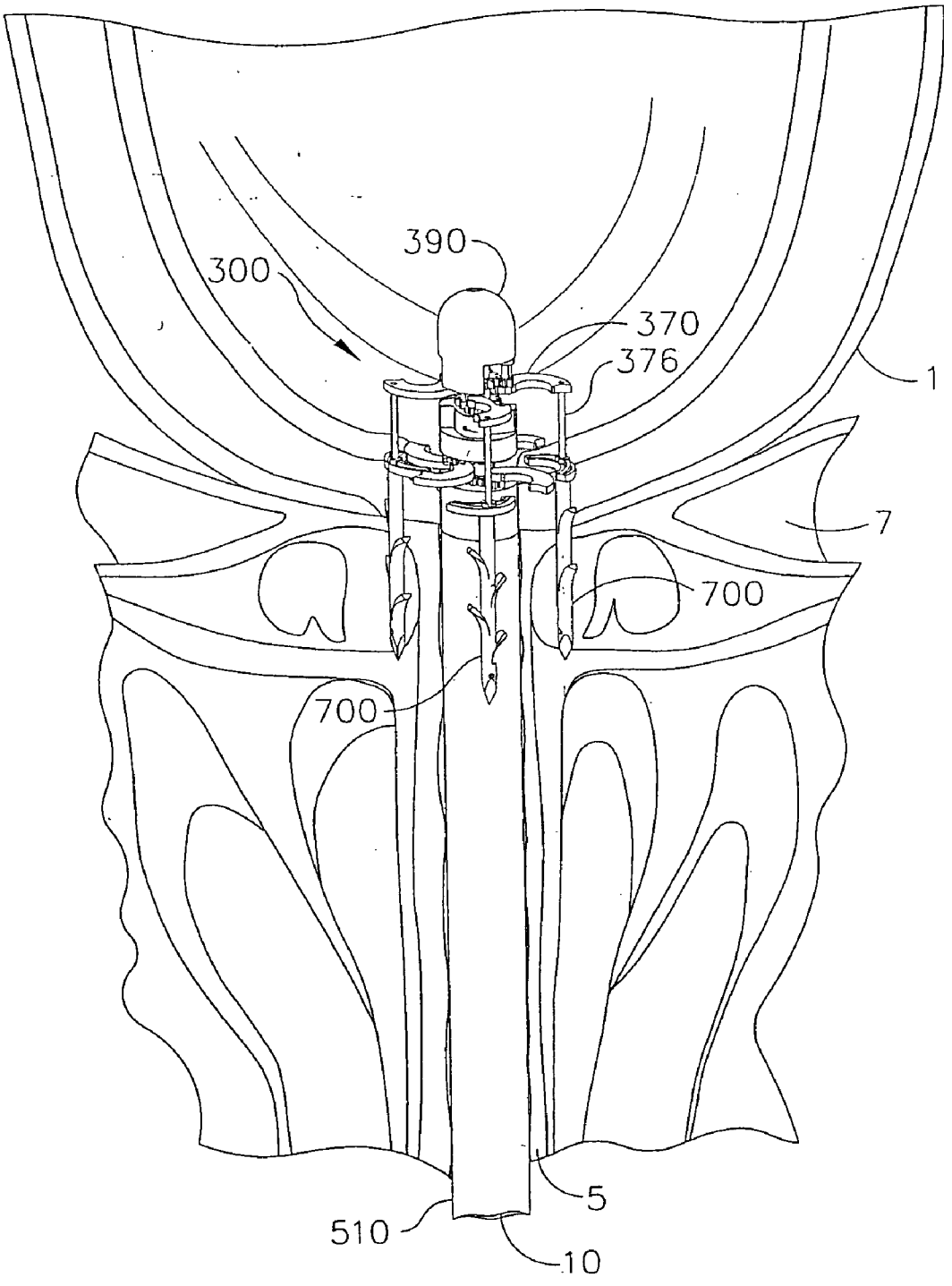

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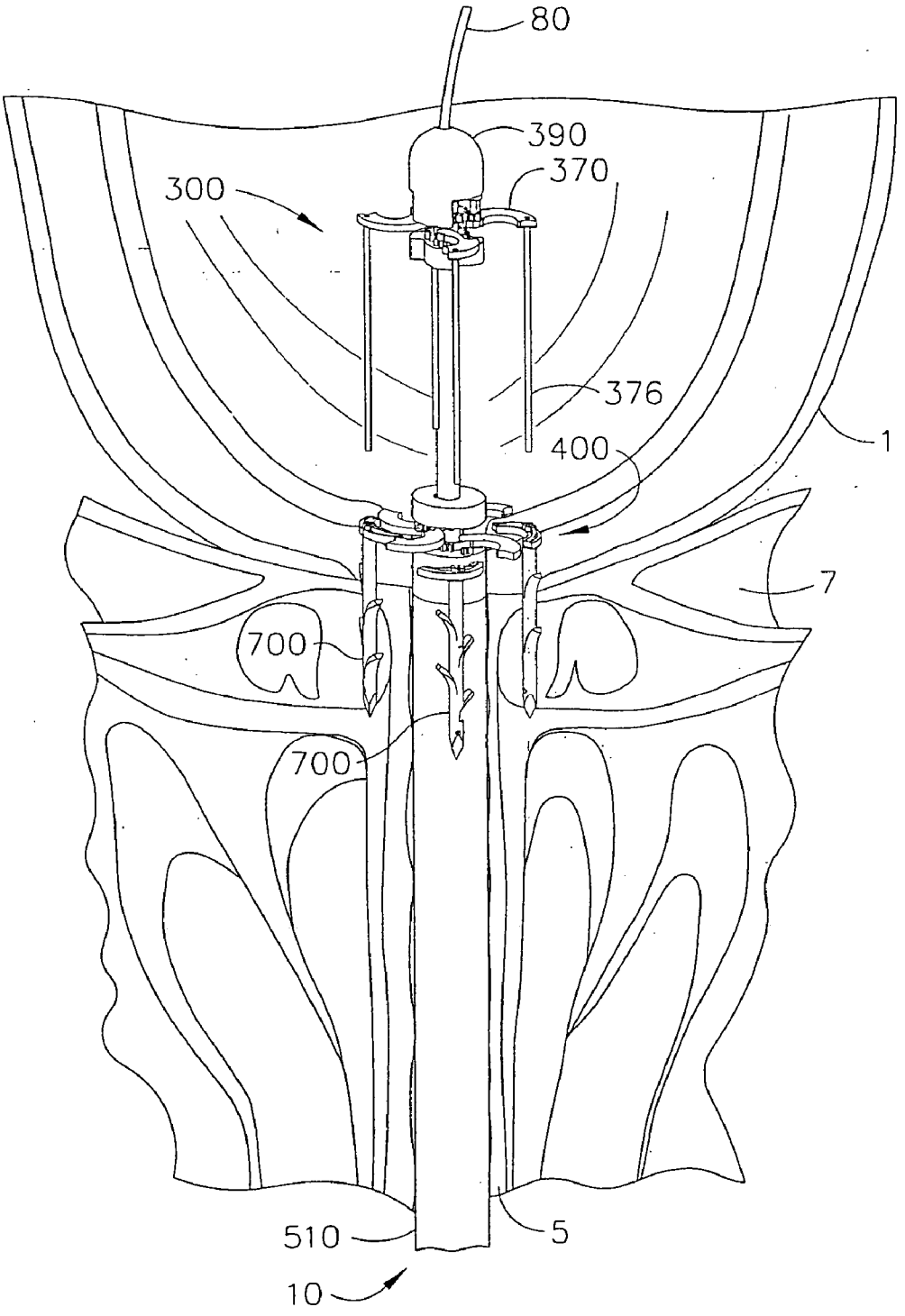

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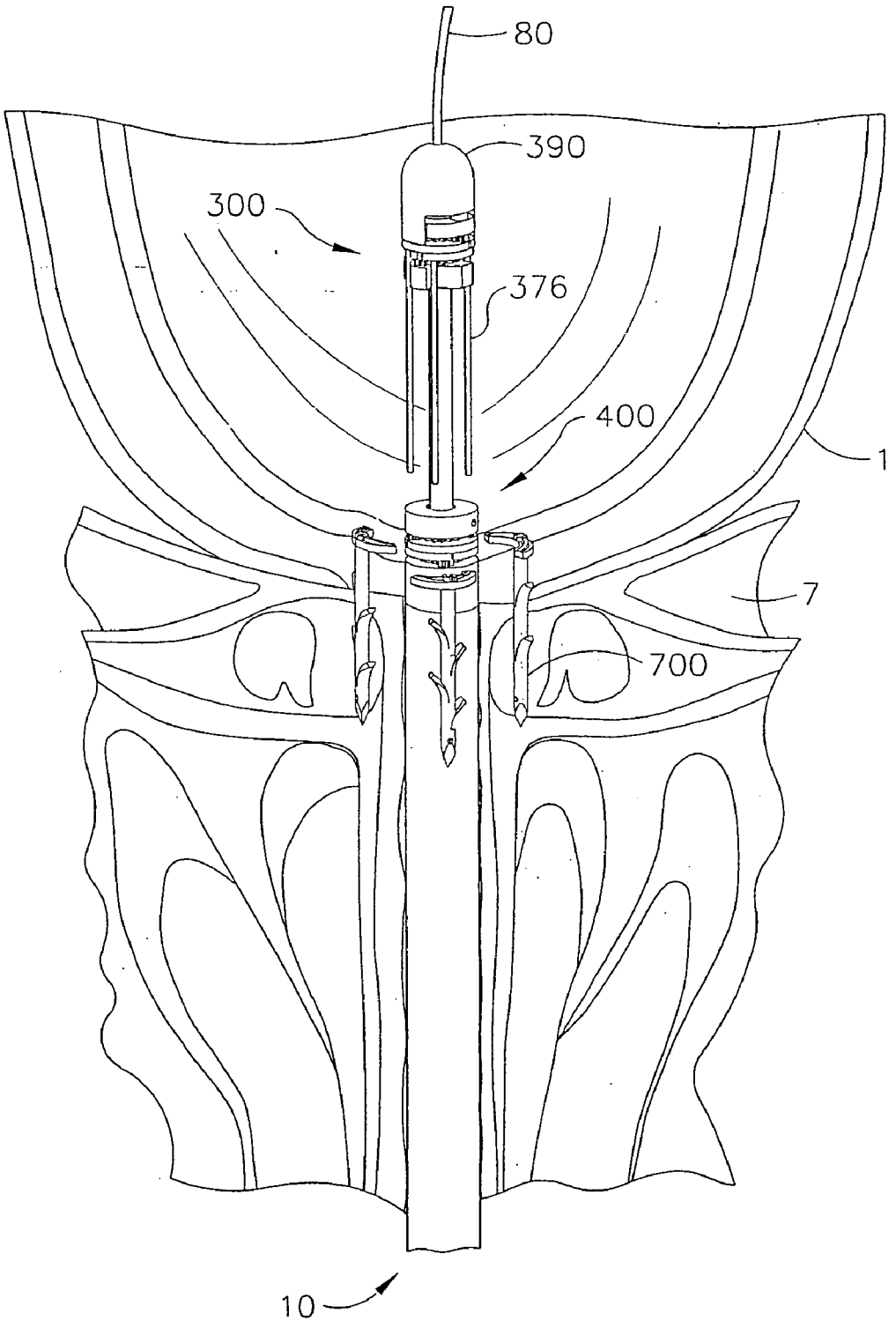

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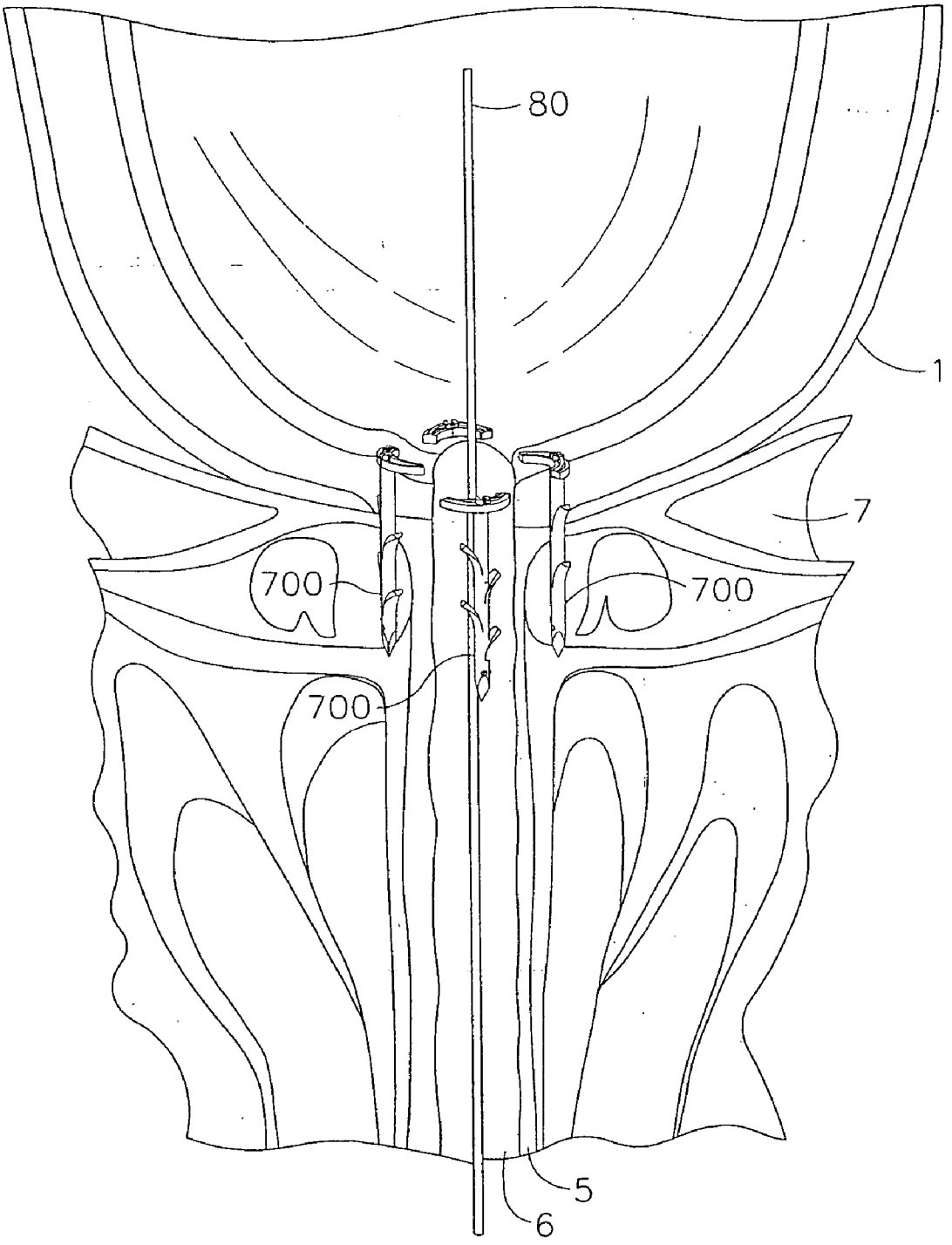

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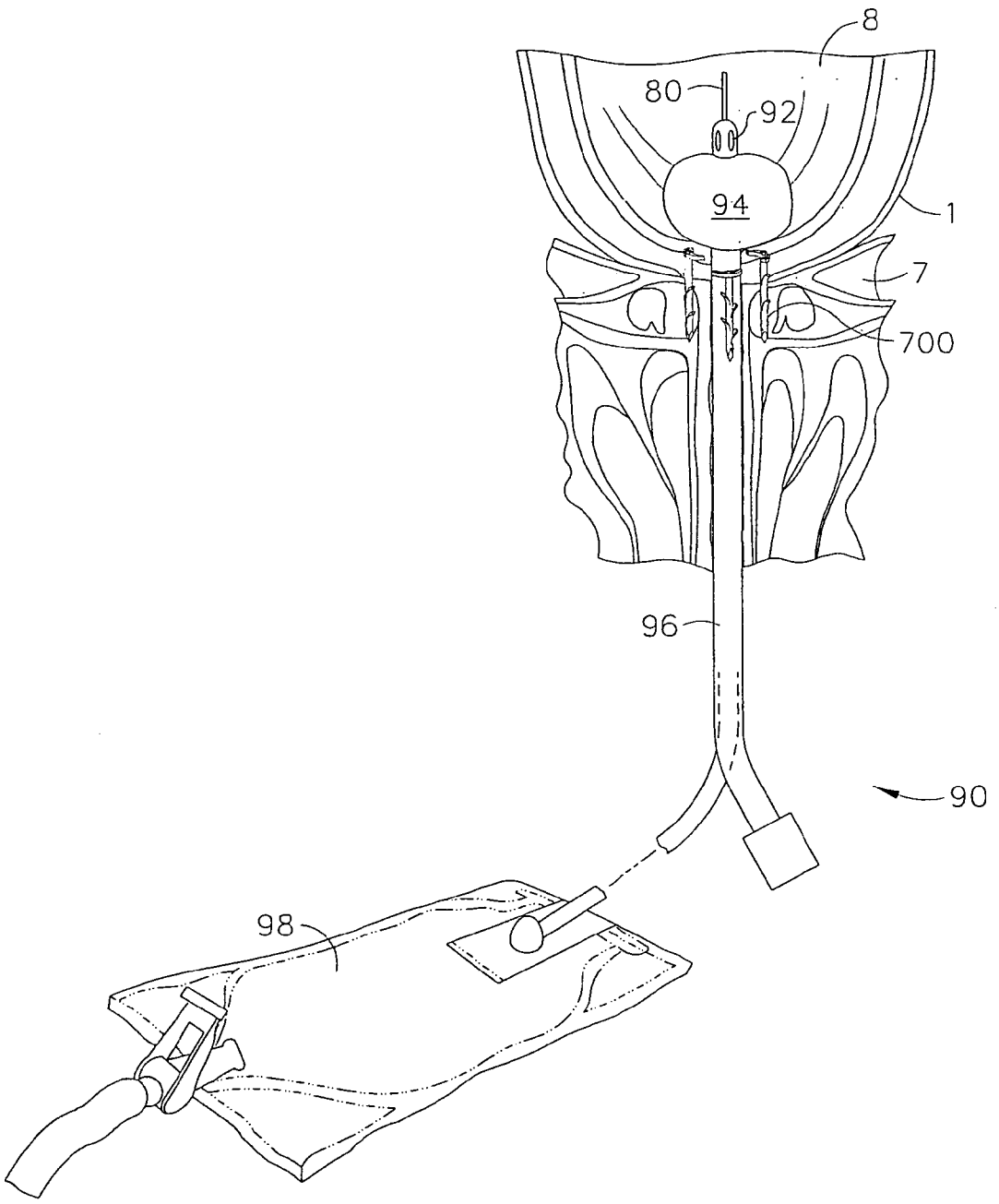

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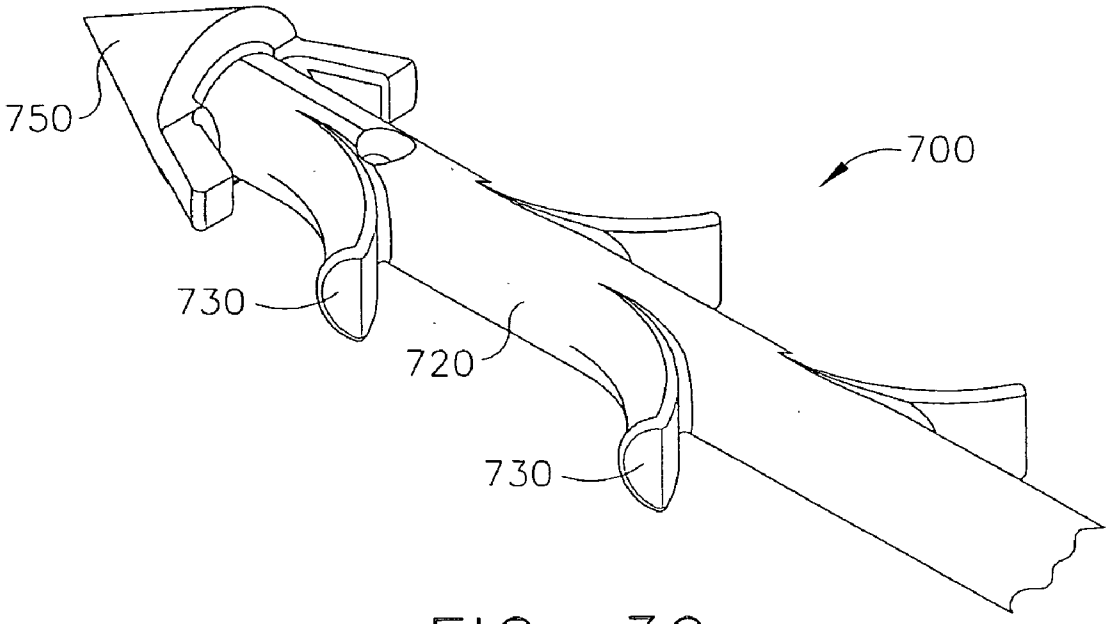

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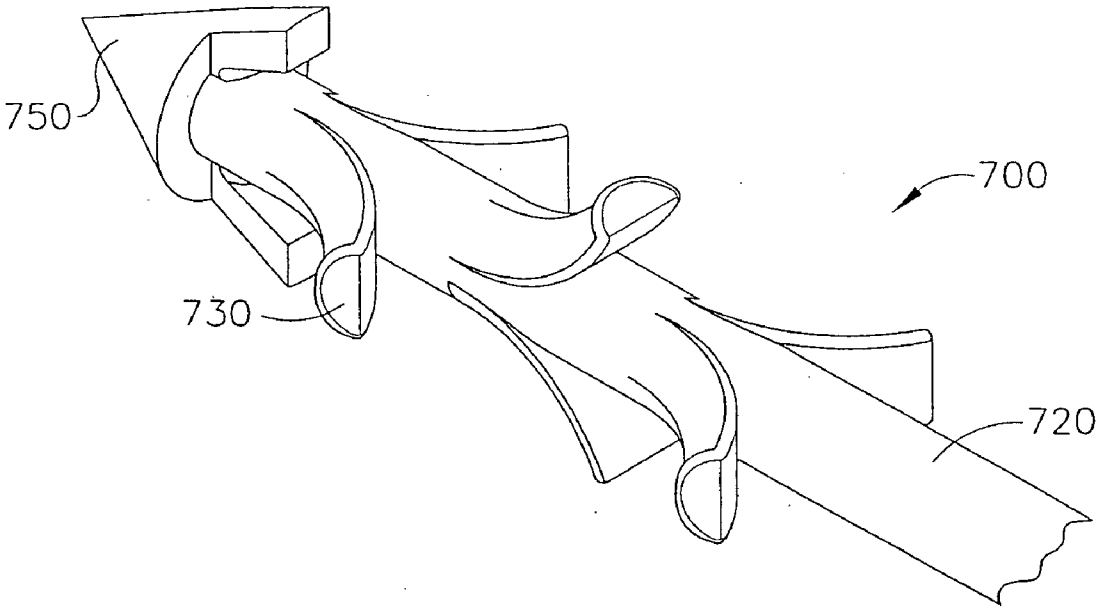

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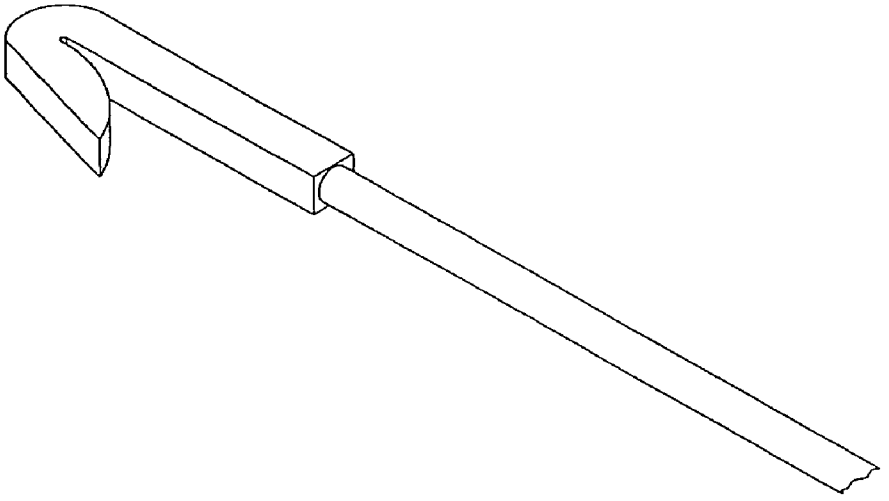

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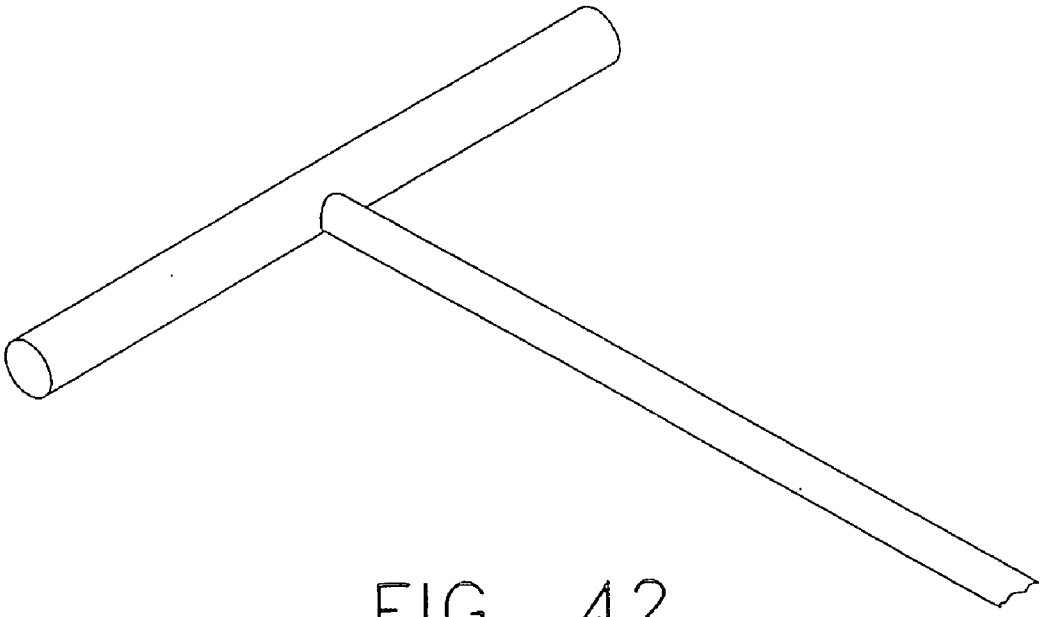

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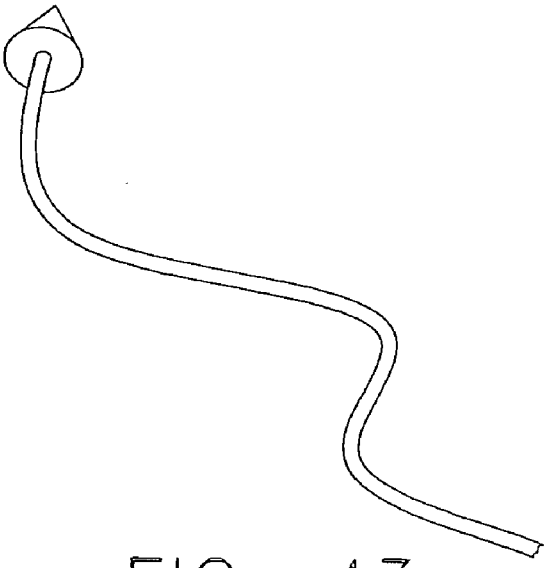

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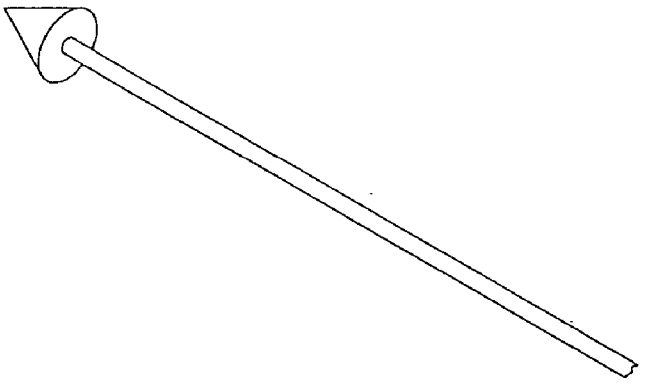


FIG. 44

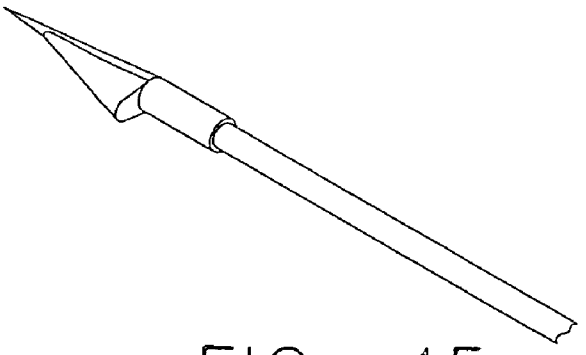
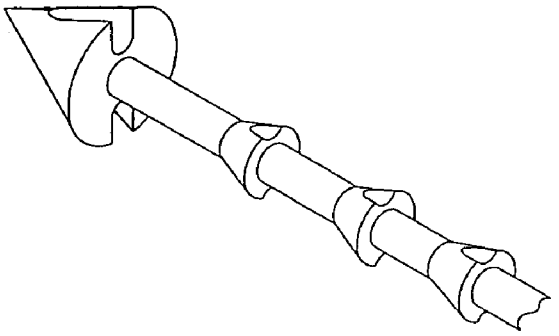


FIG. 45



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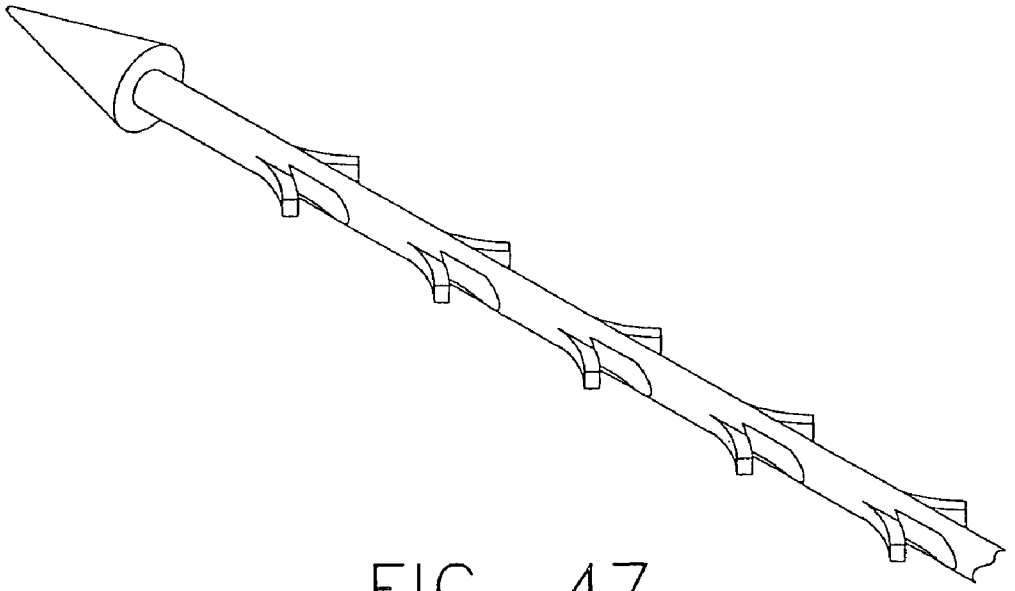

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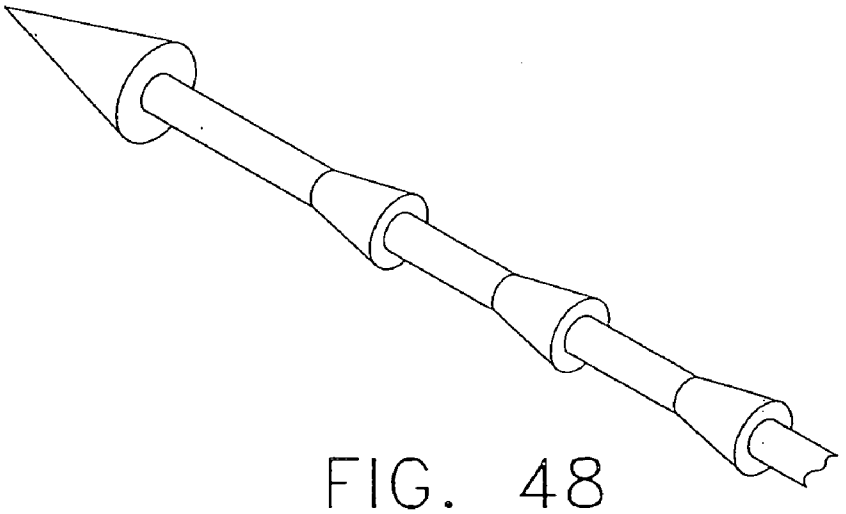

FIG. 48

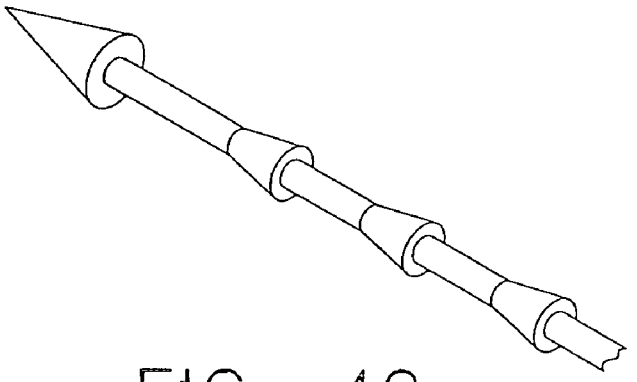

FIG. 49

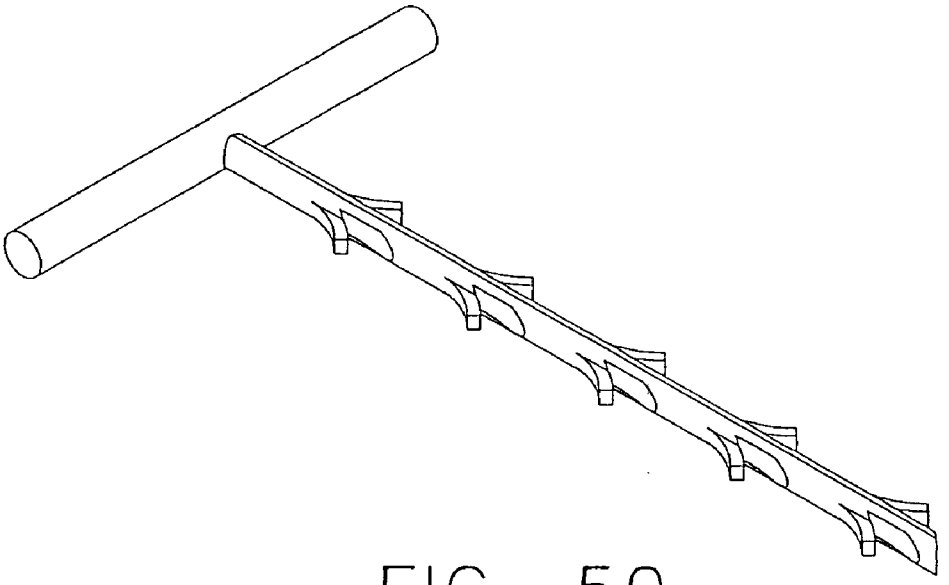

FIG. 50

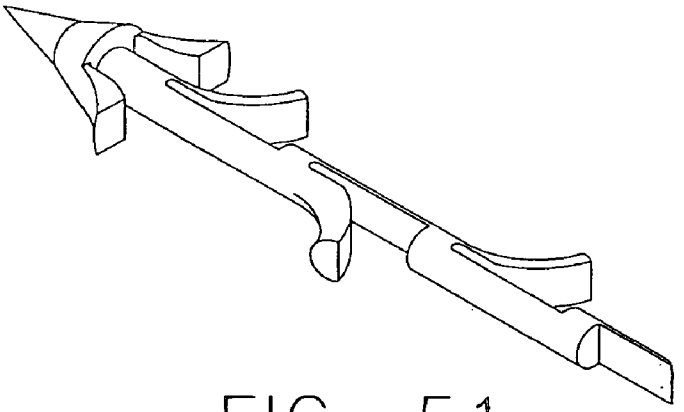

FIG. 51

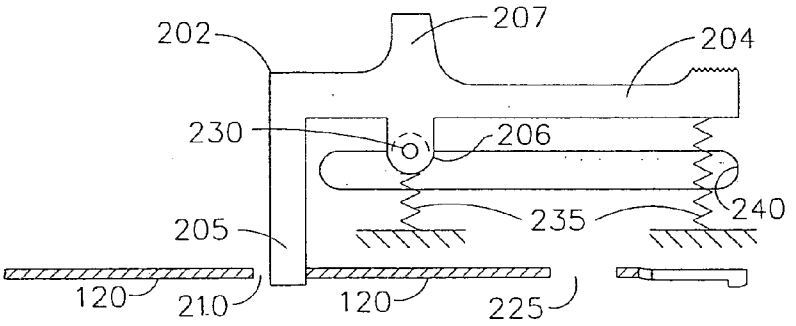

FIG. 52

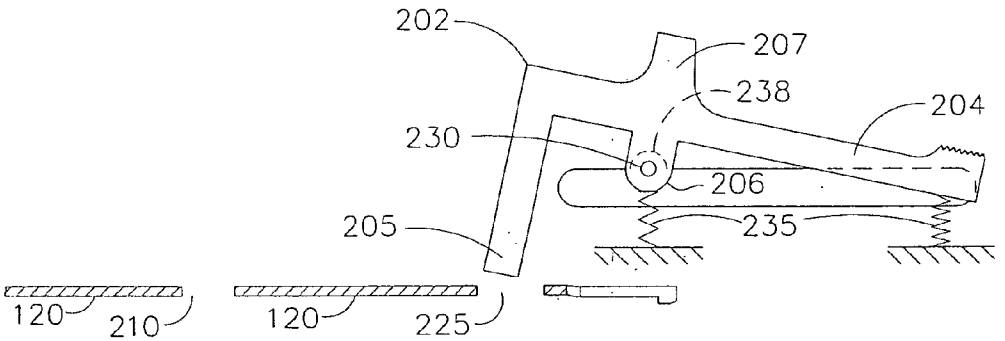

FIG. 53

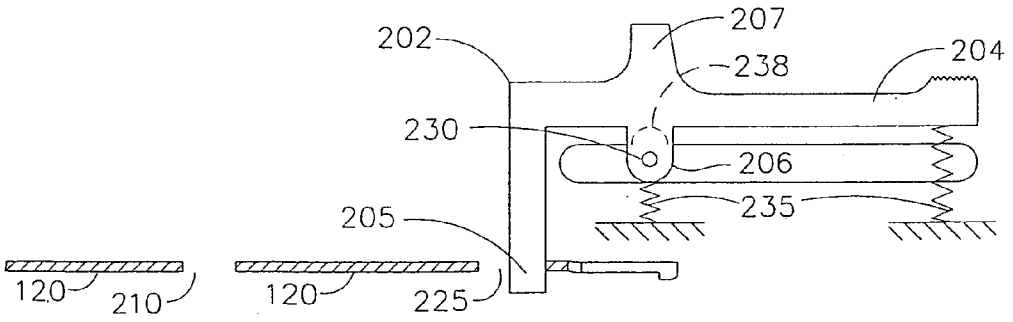

FIG. 54

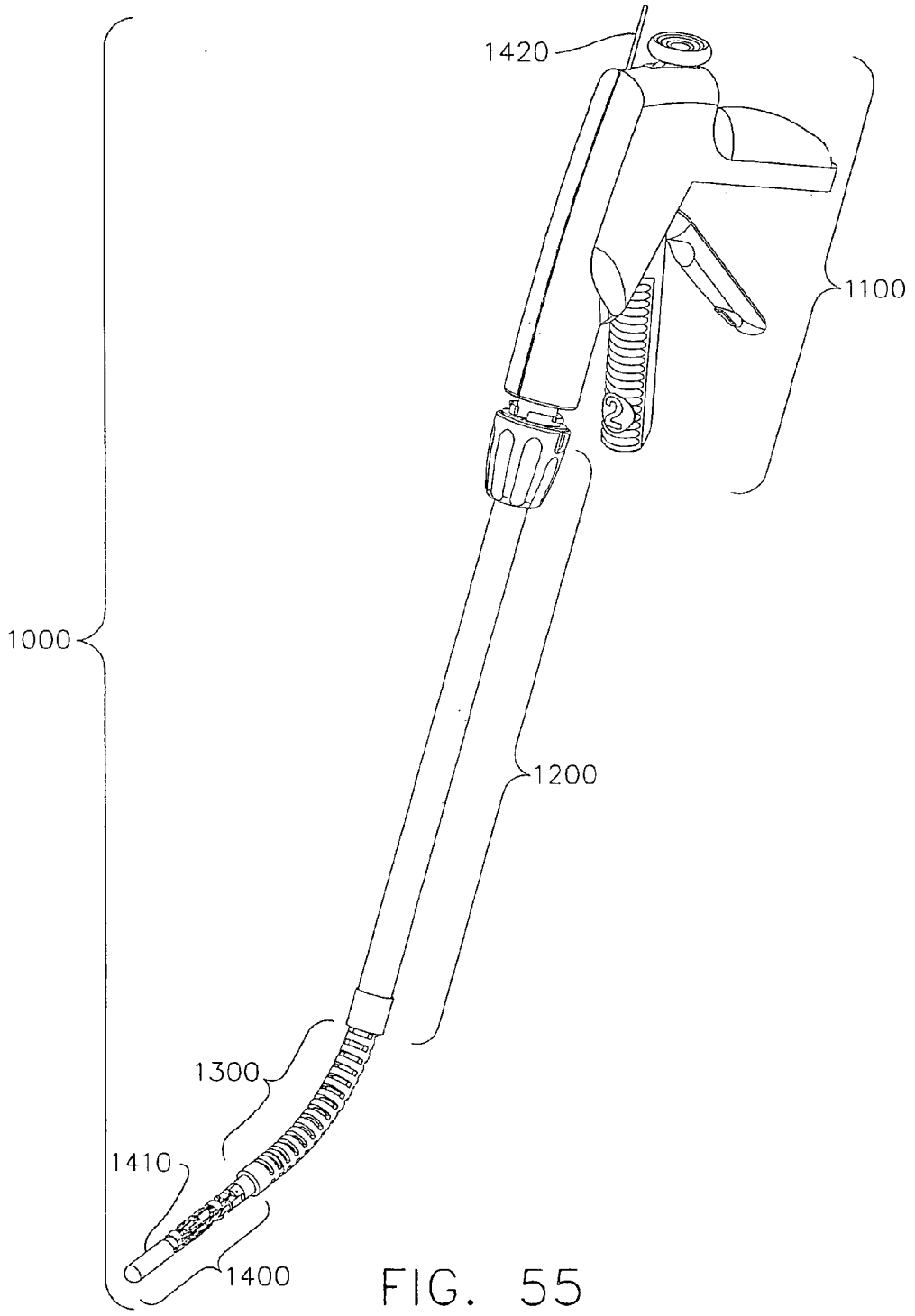

FIG. 55

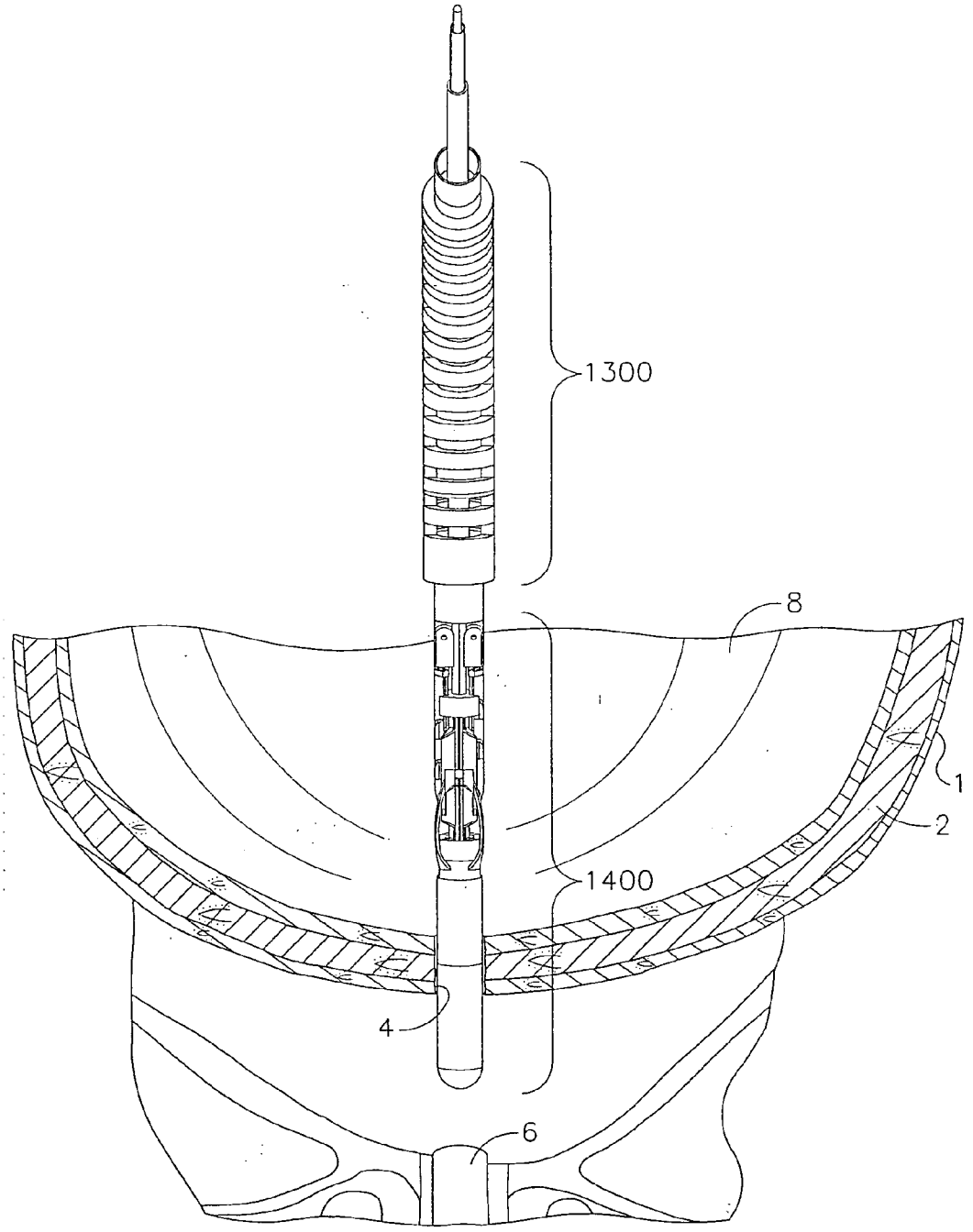

FIG. 56

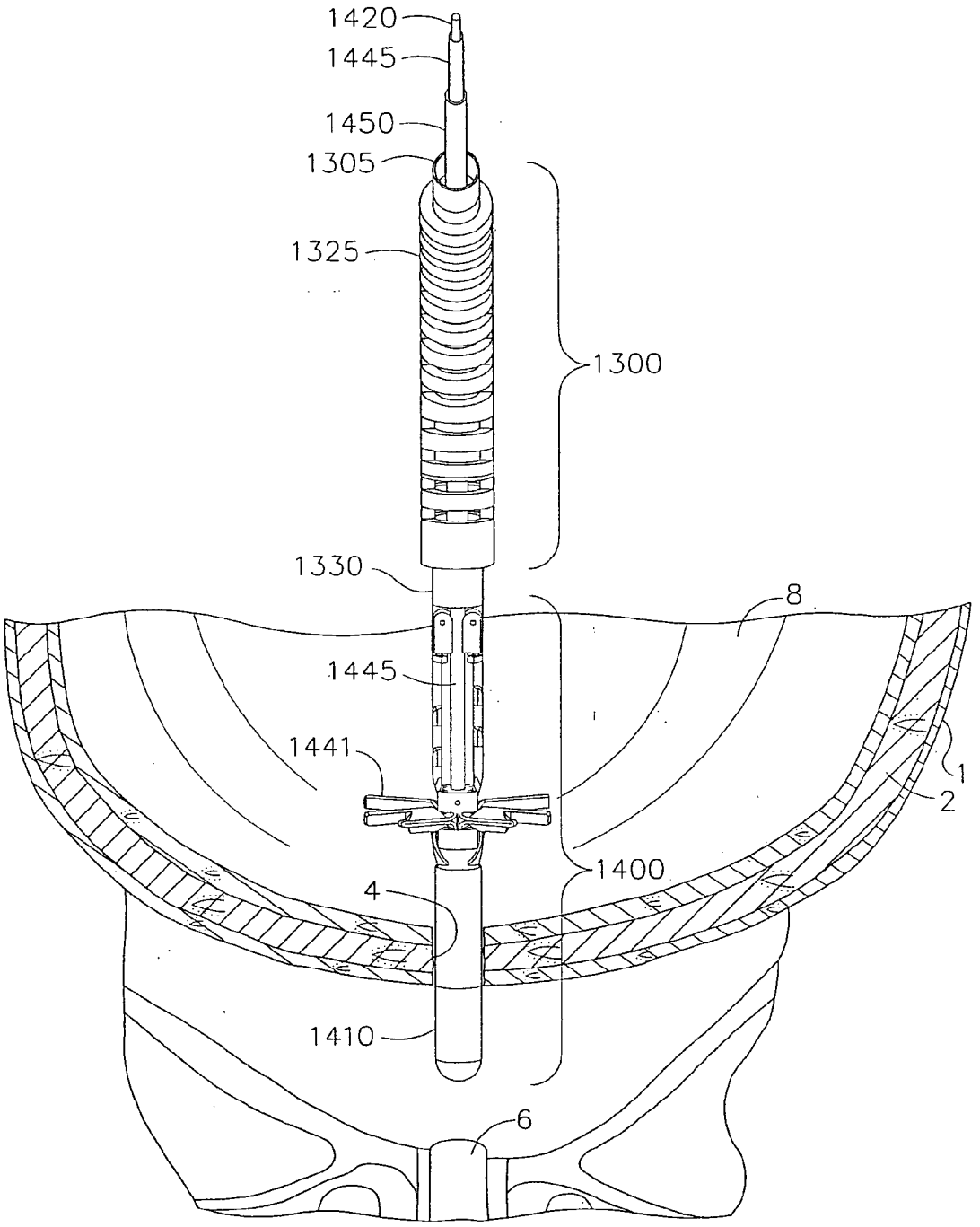

FIG. 57

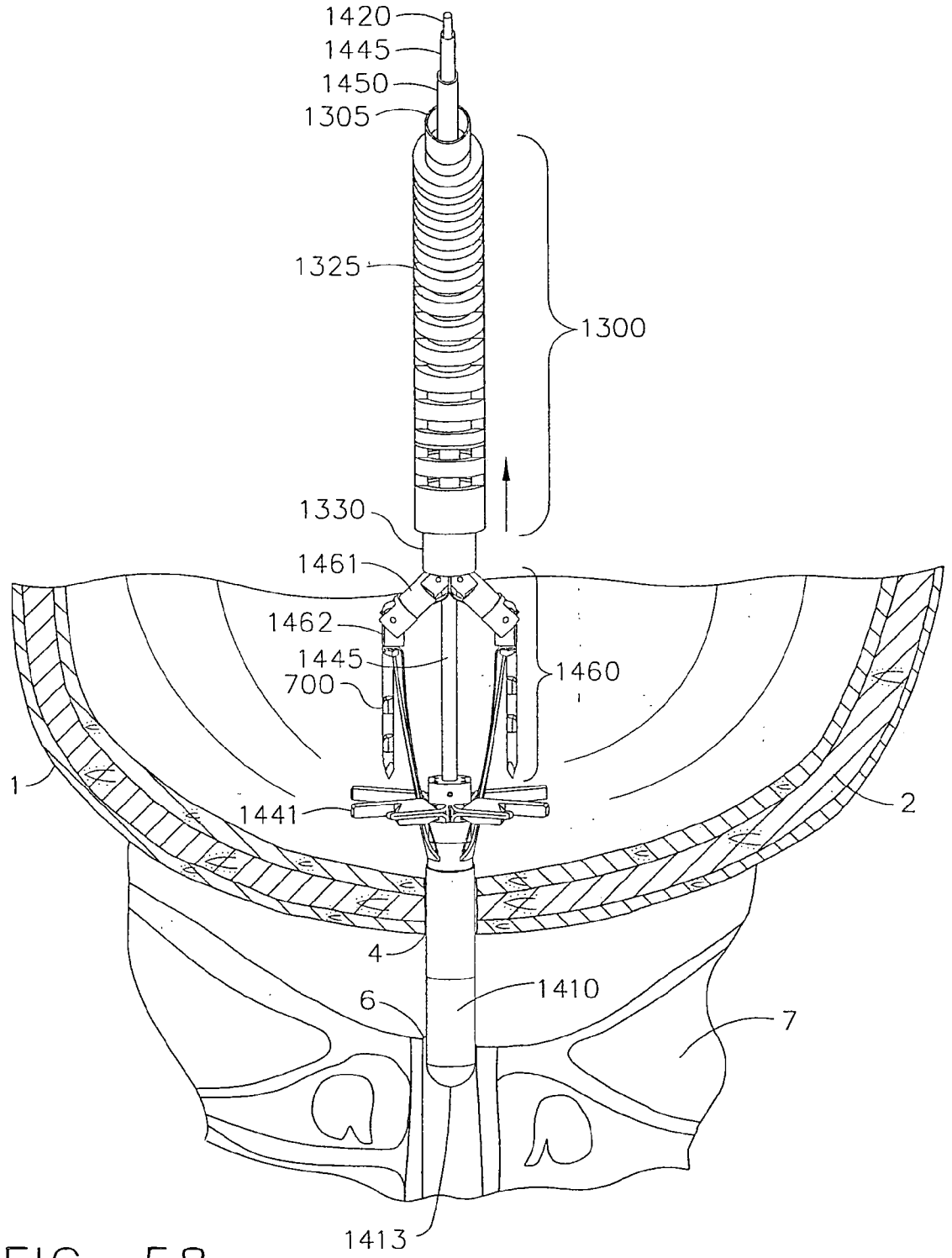
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FIG. 58

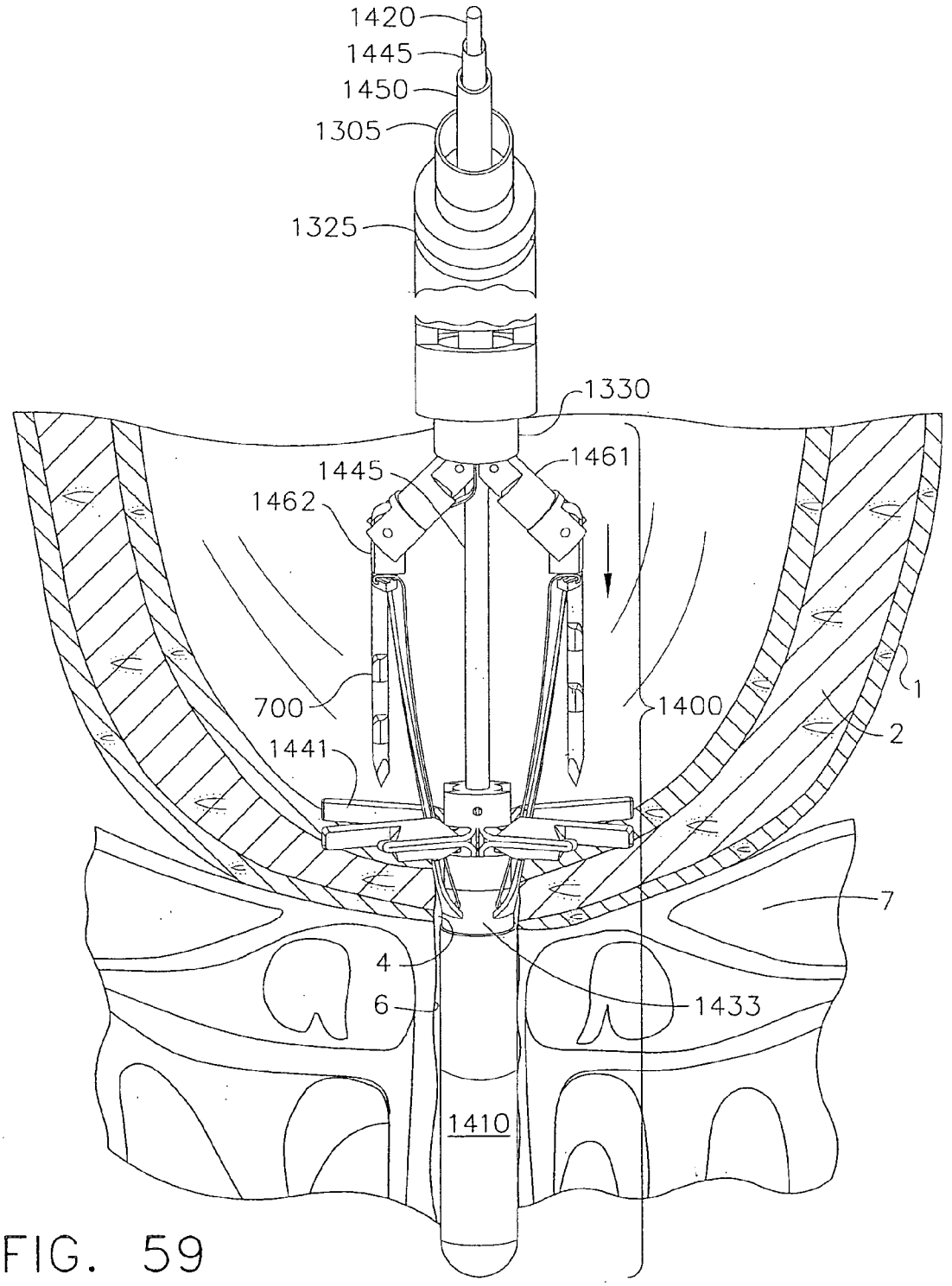
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FIG. 59

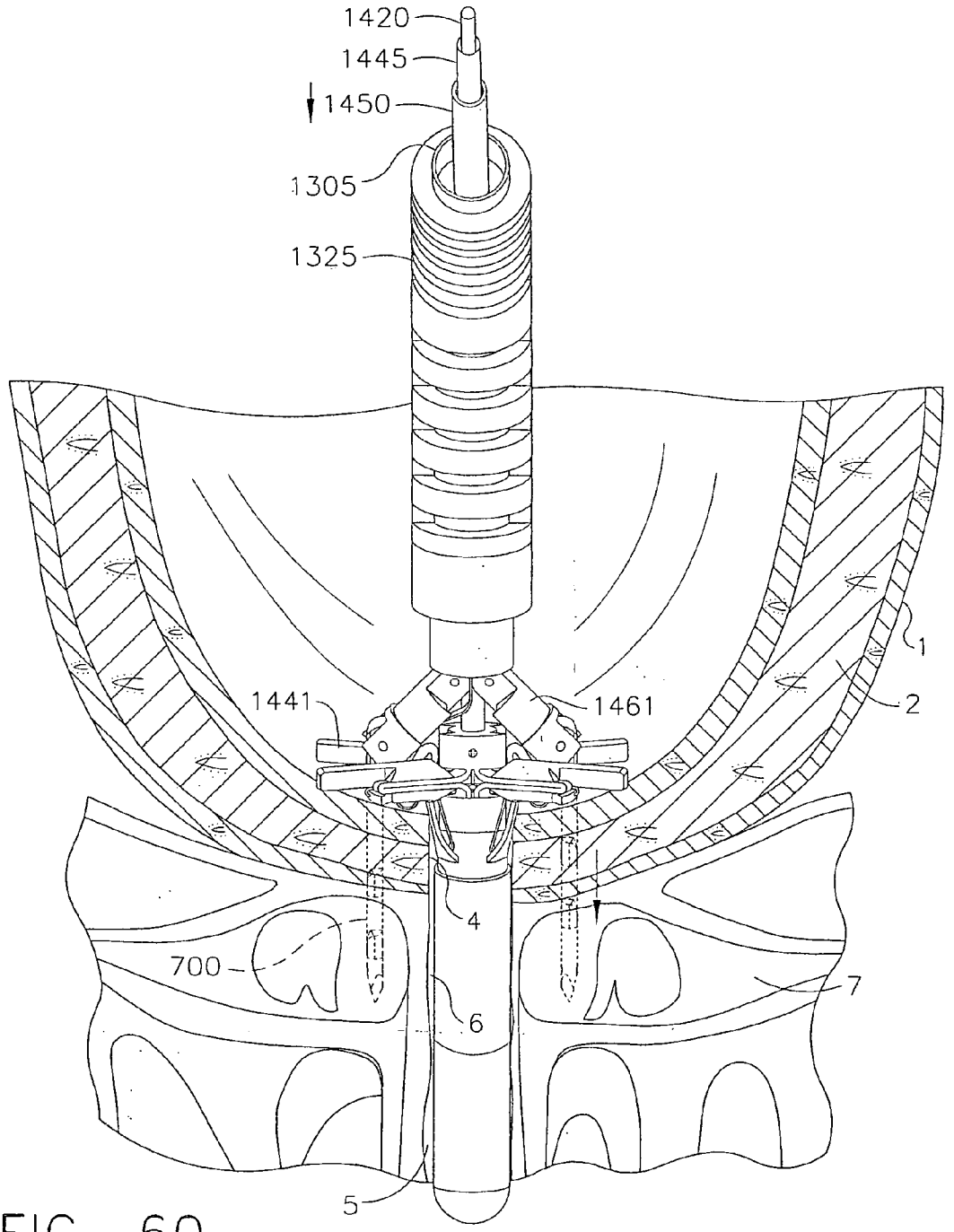

FIG. 60

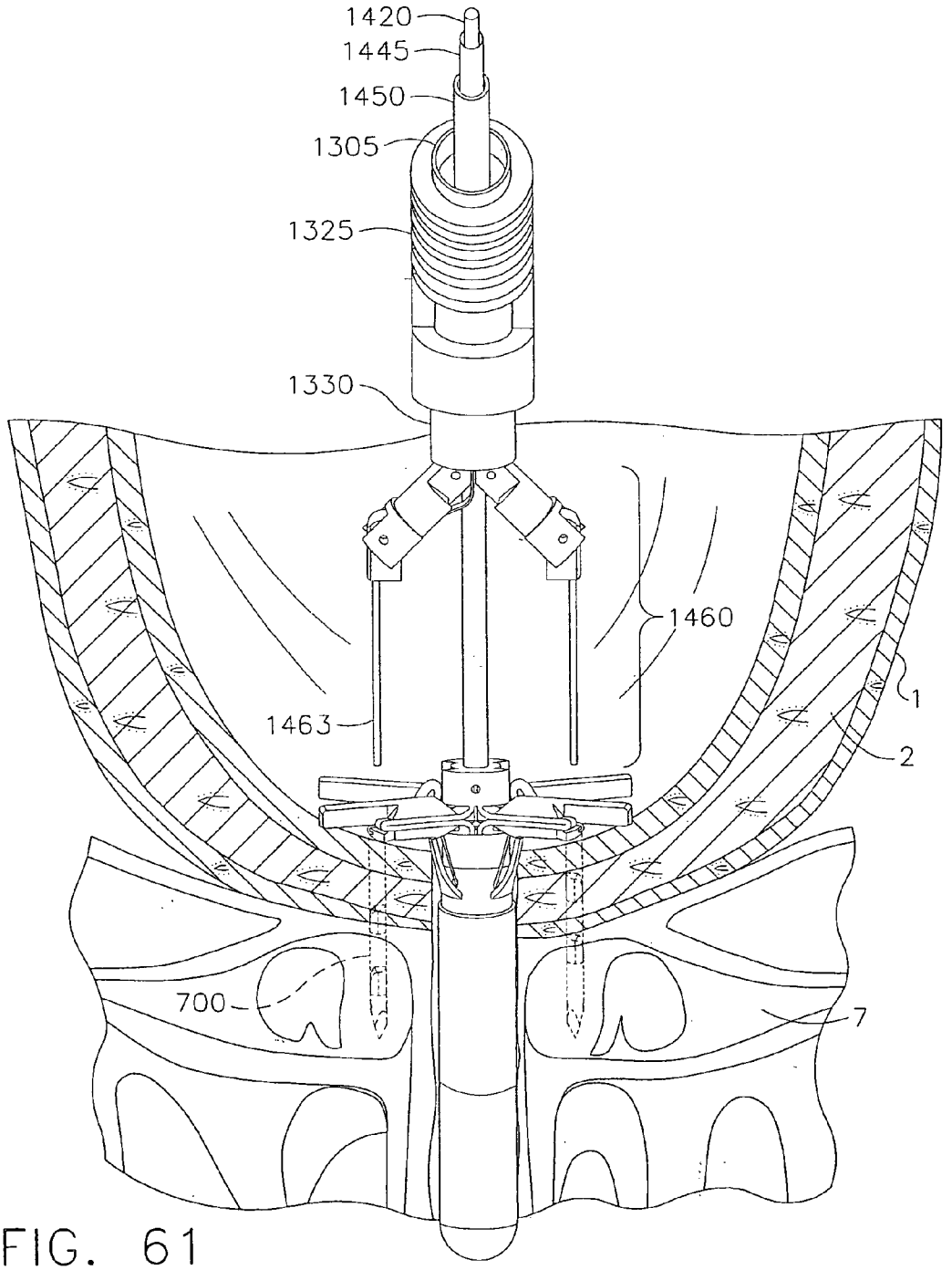

FIG. 61

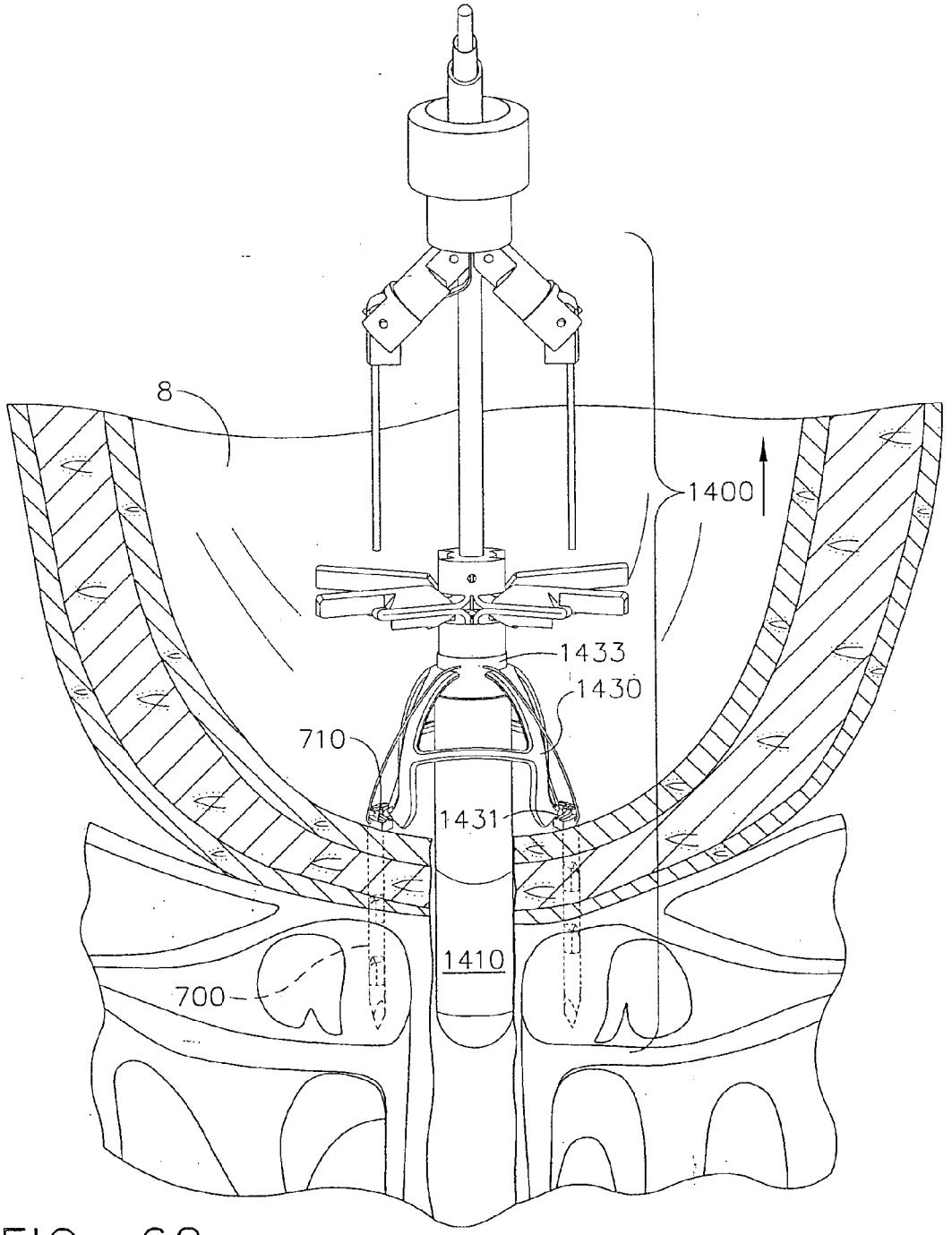

FIG. 62

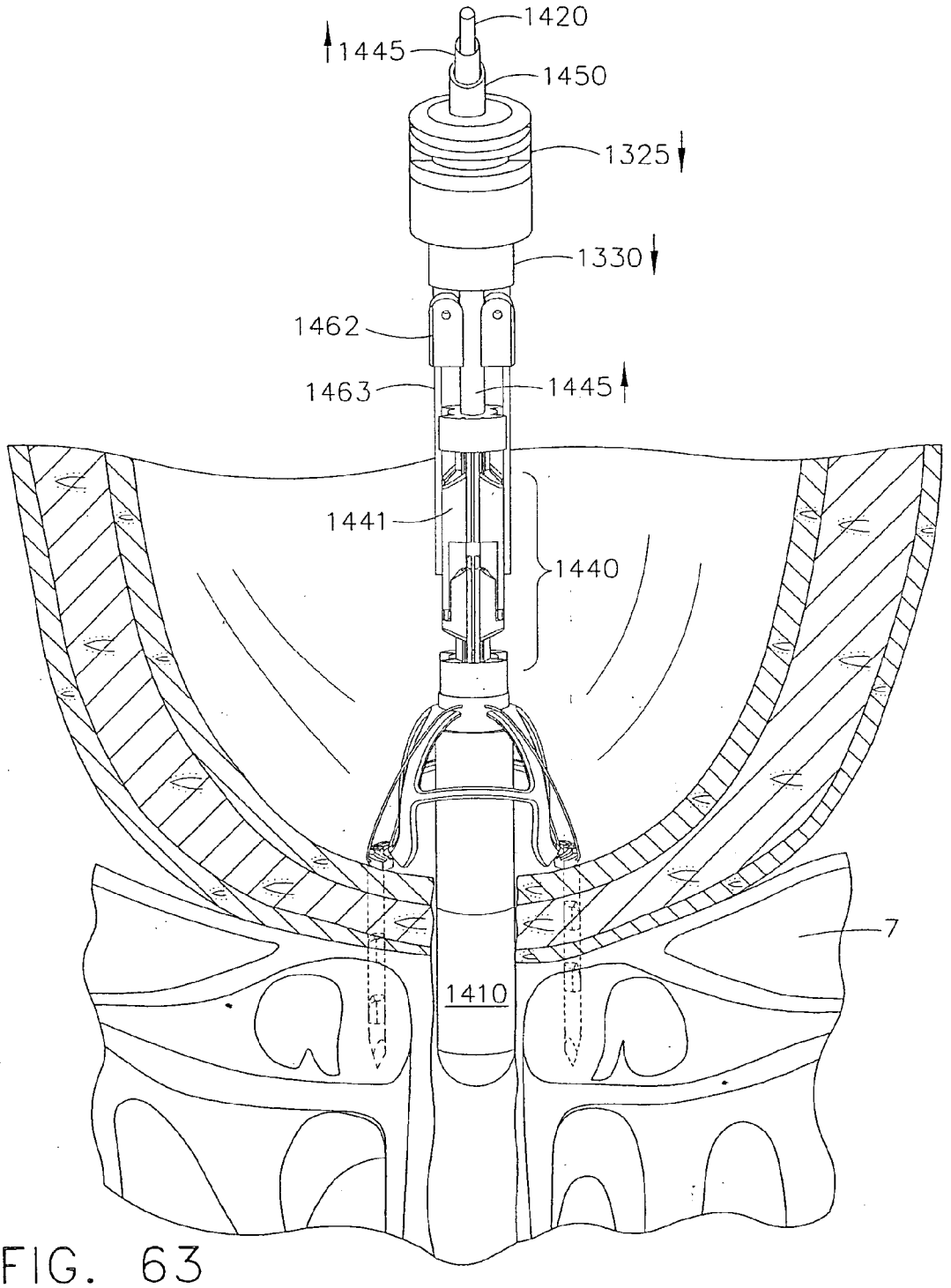

FIG. 63

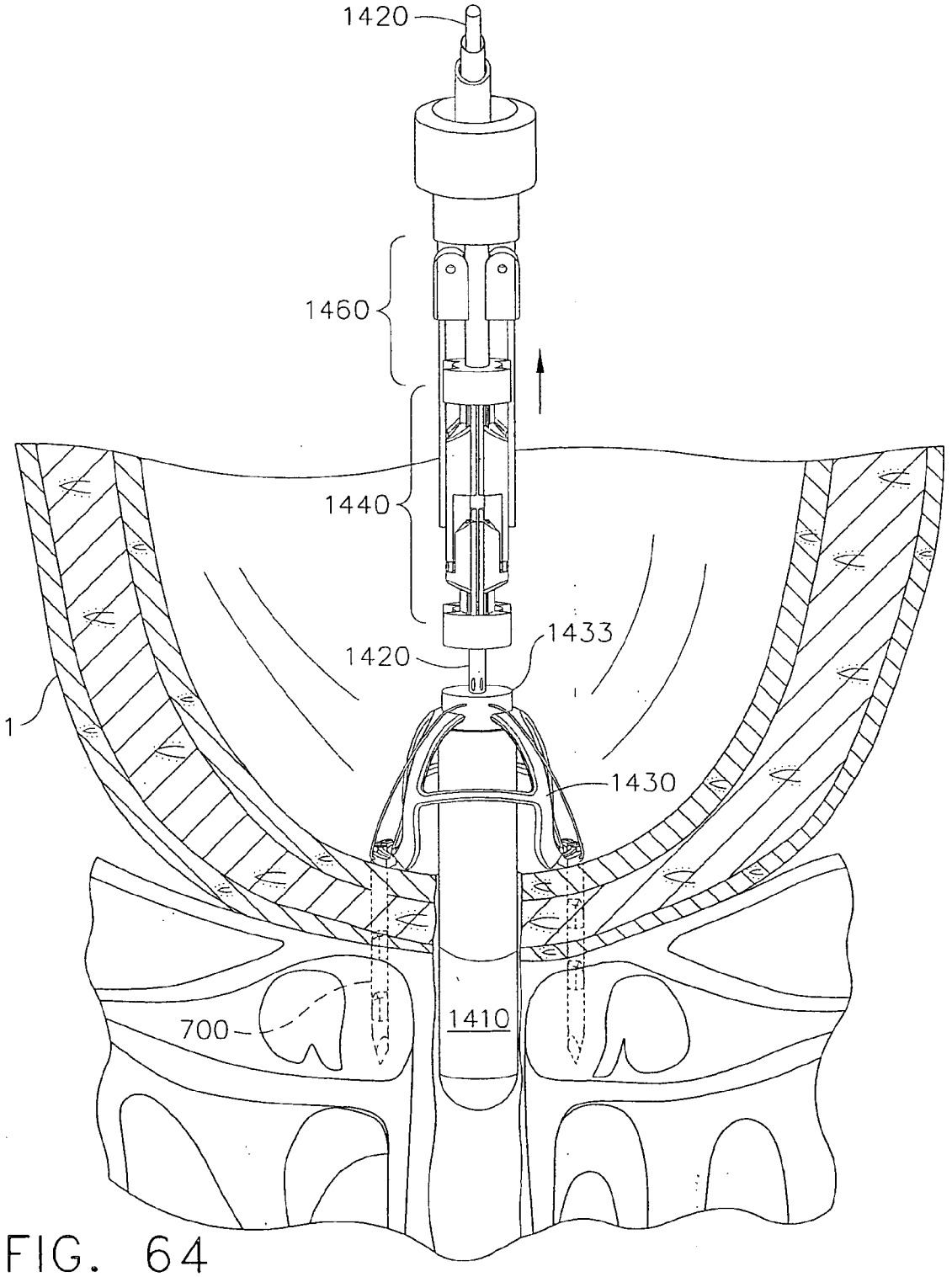

FIG. 64

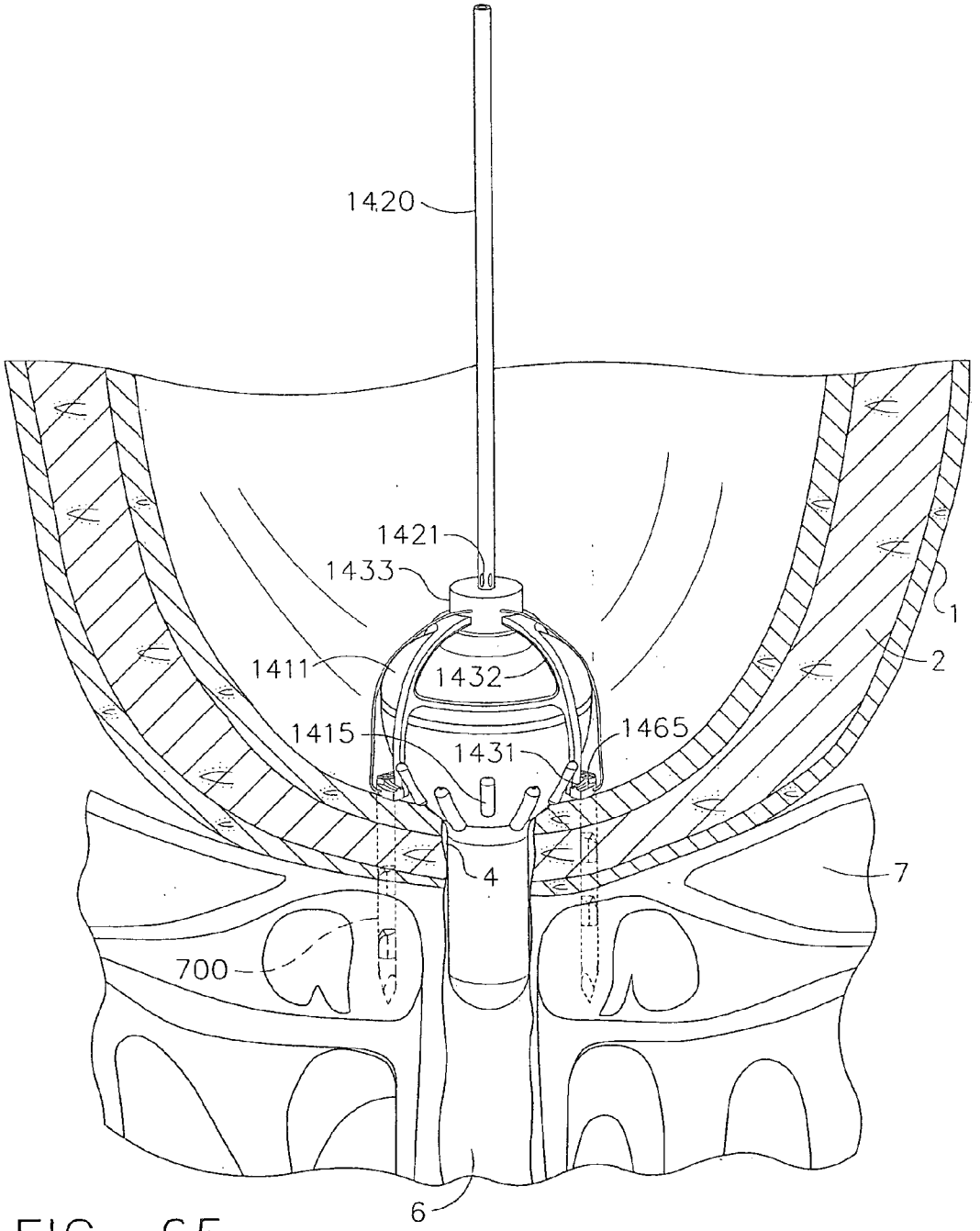

FIG. 65

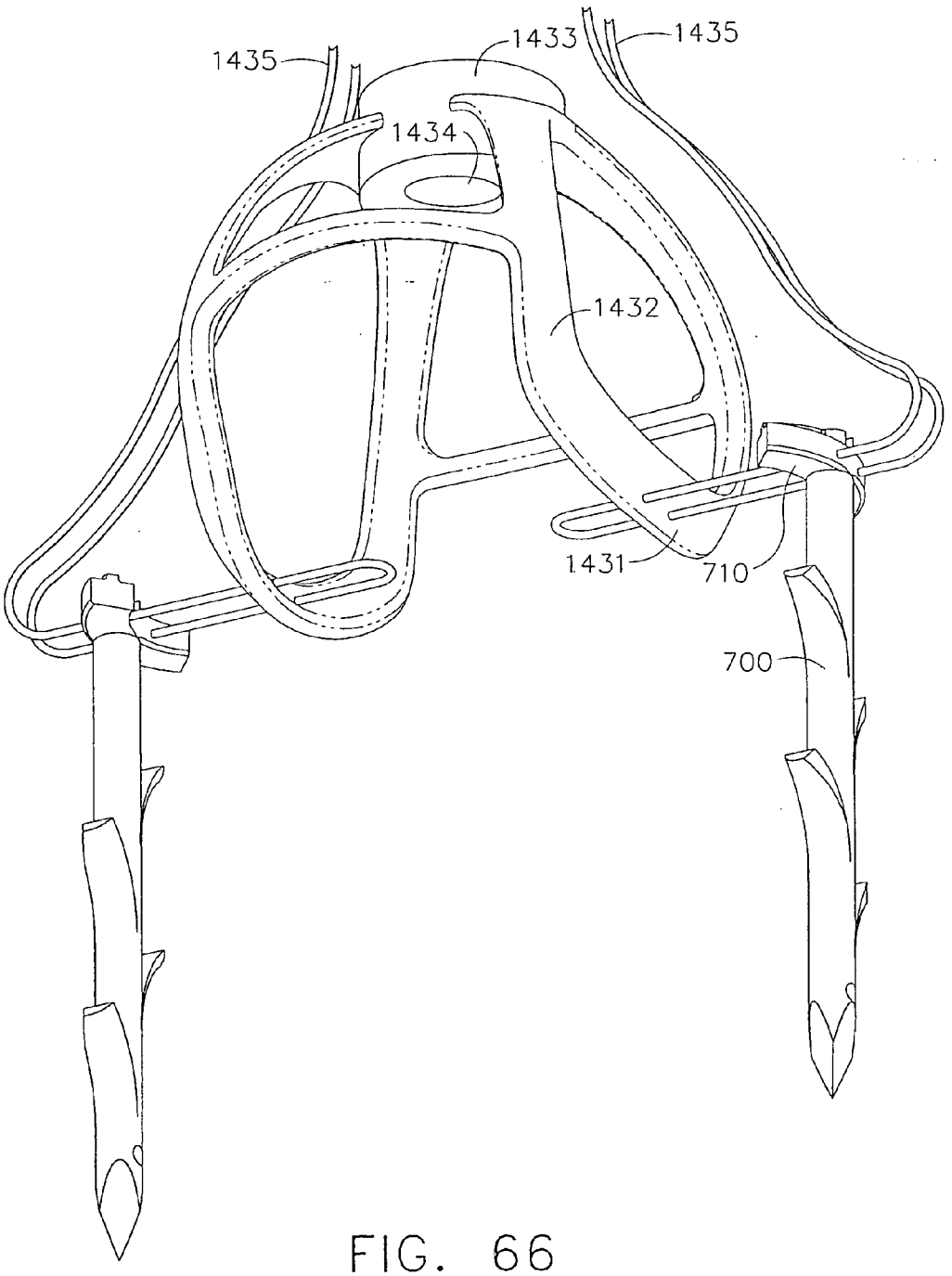

FIG. 66

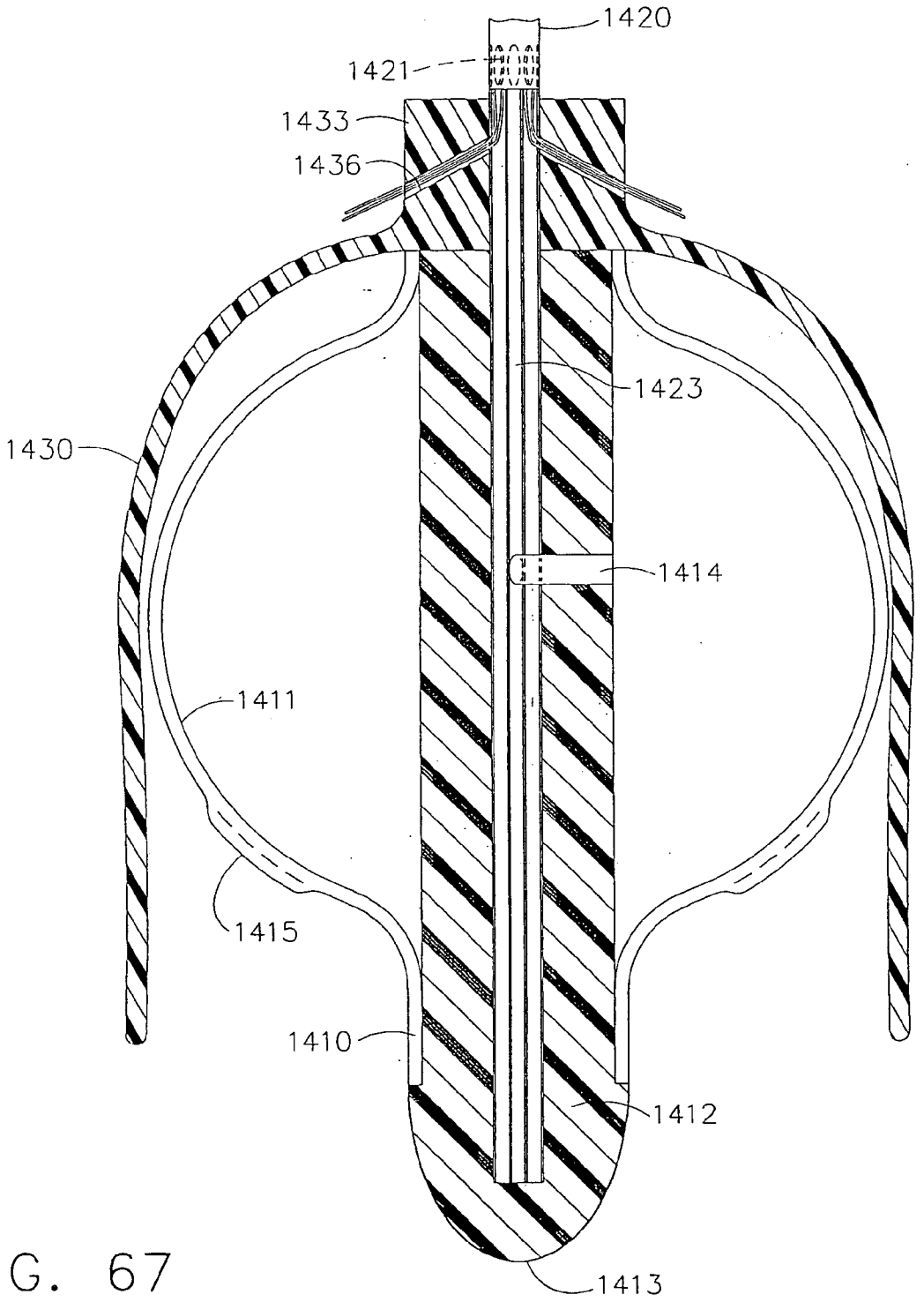

FIG. 67

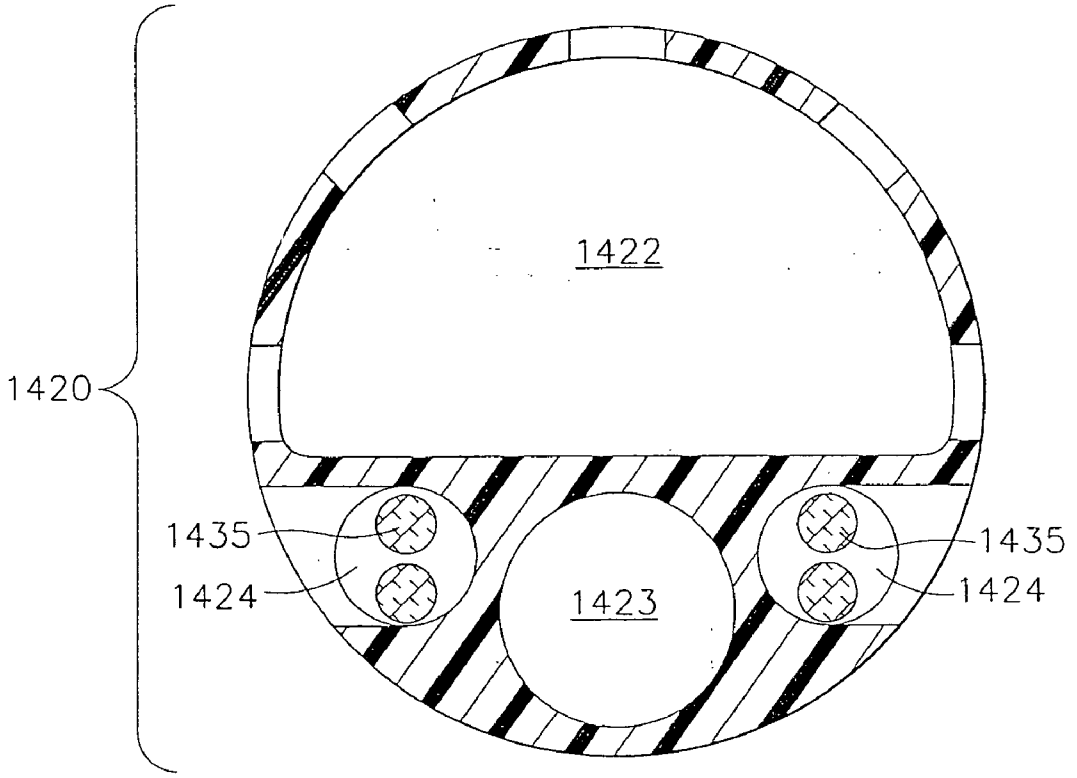

FIG. 68

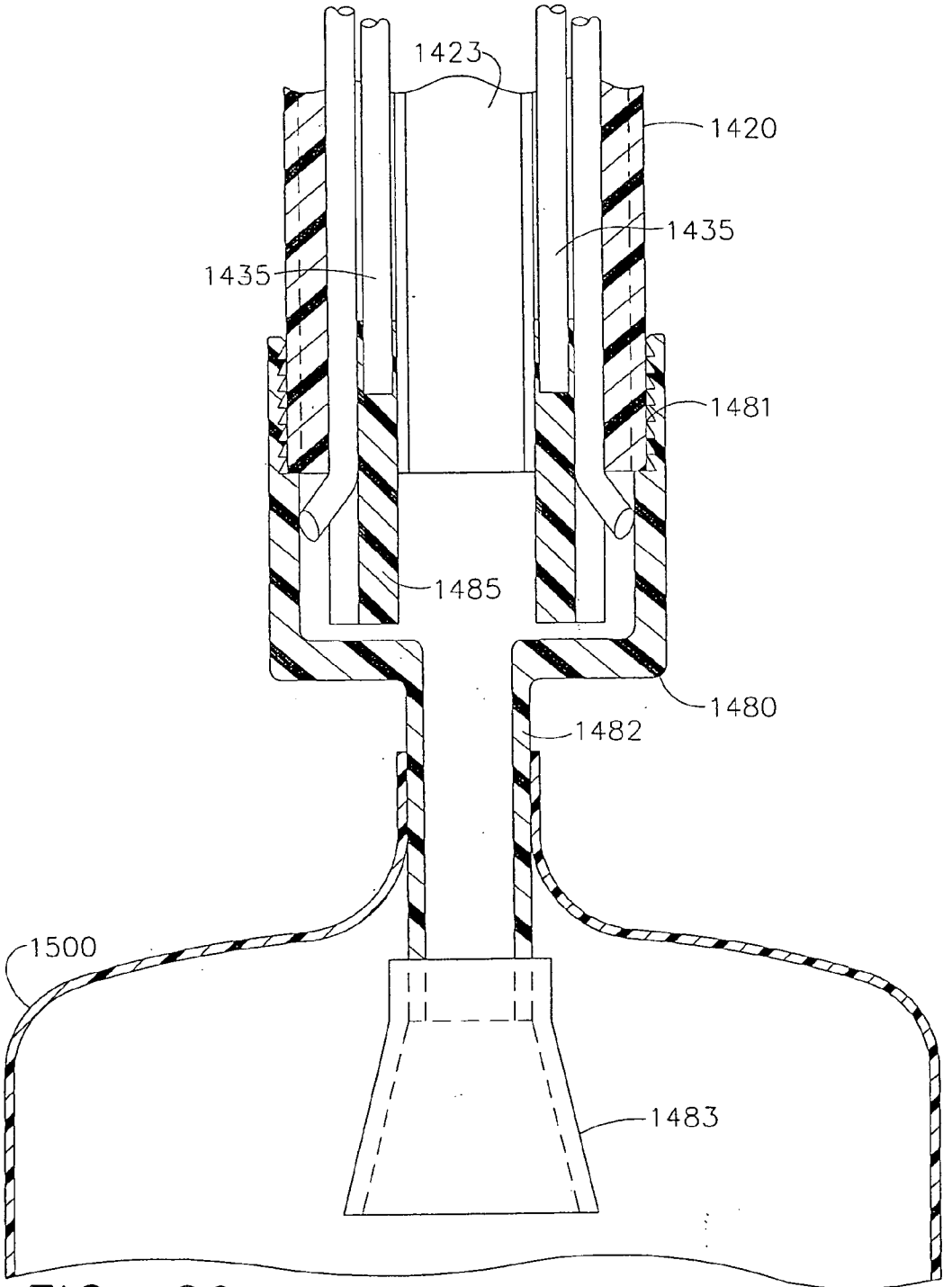

FIG. 69

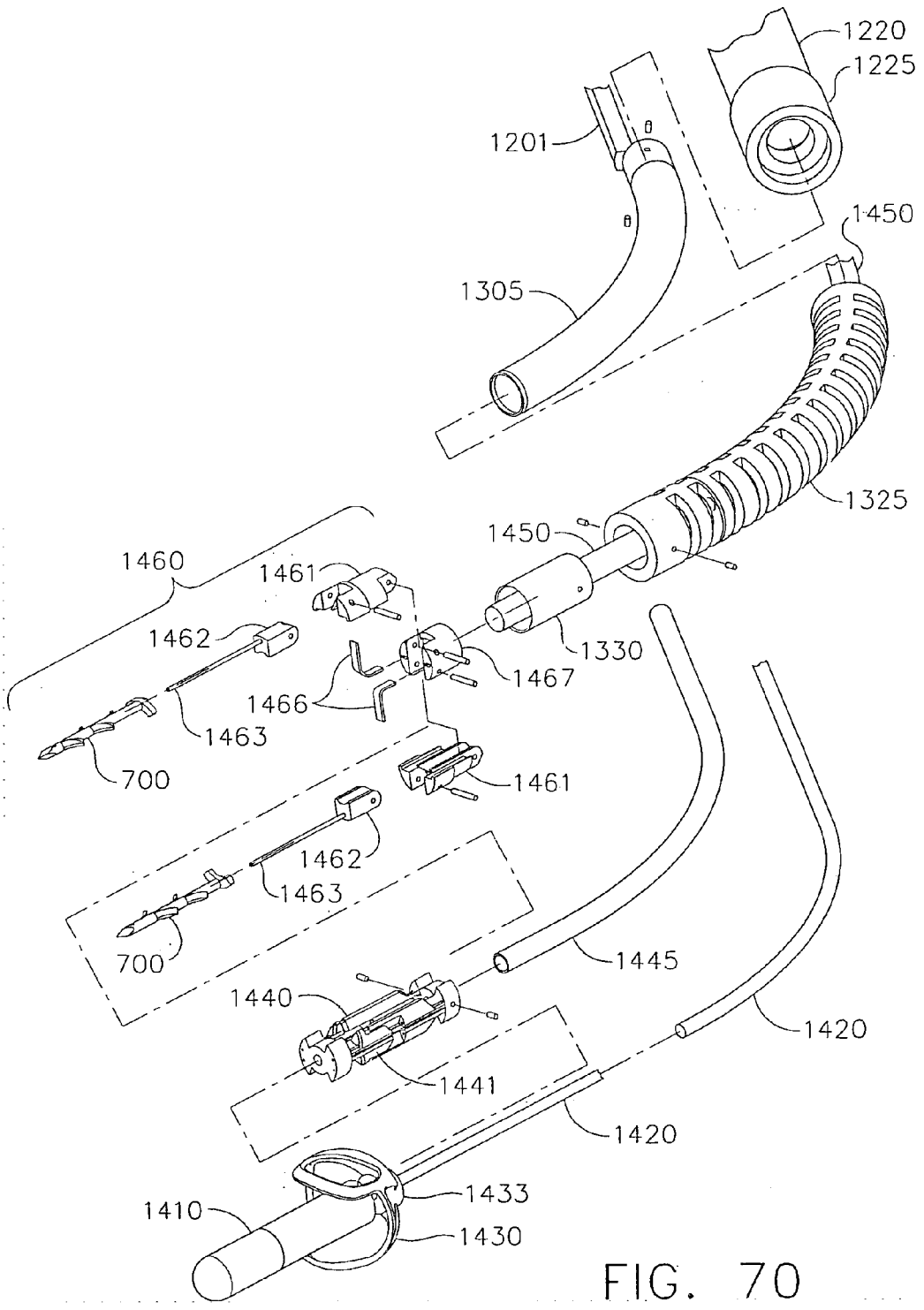
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FIG. 70

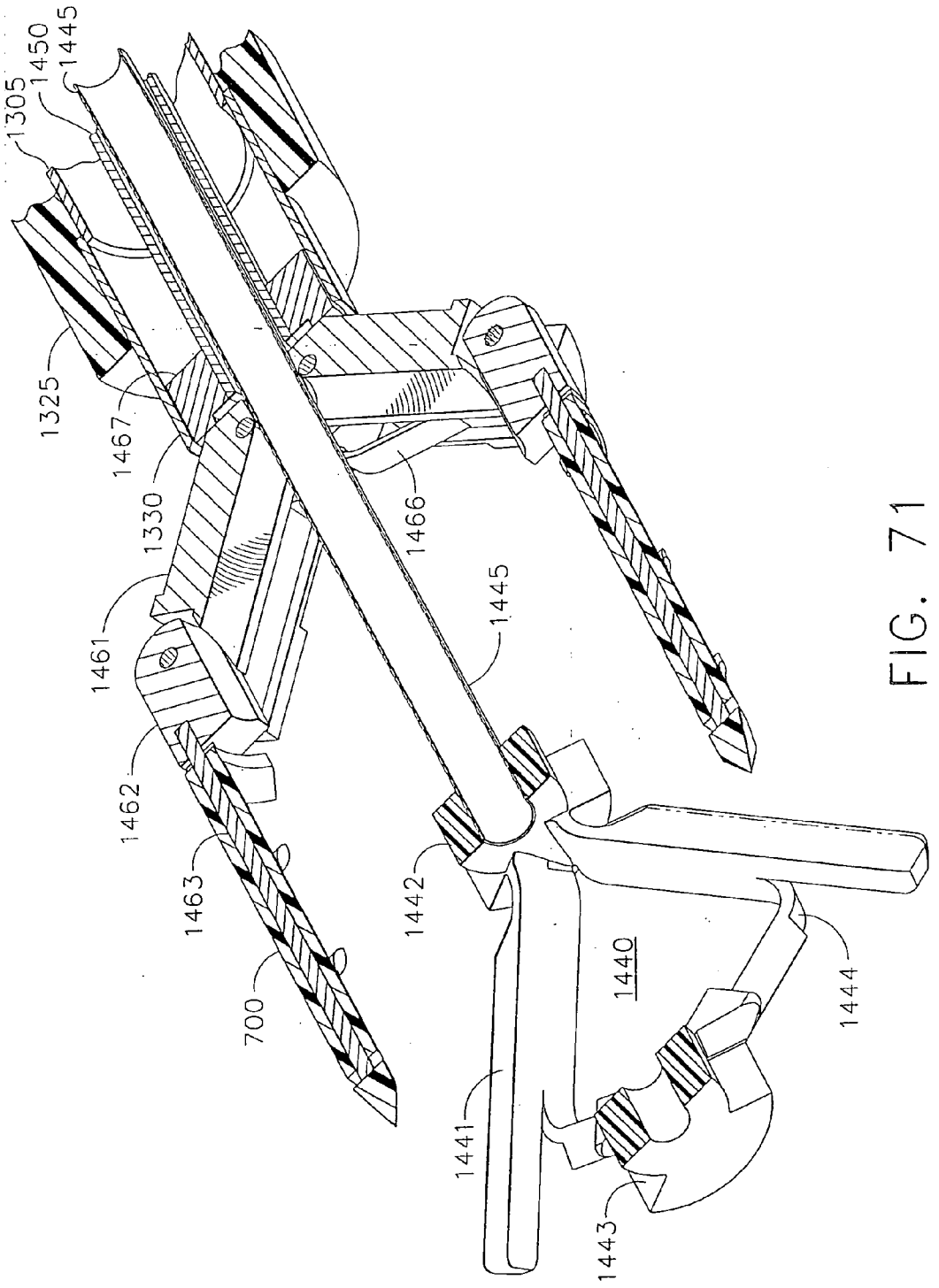
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FIG. 71

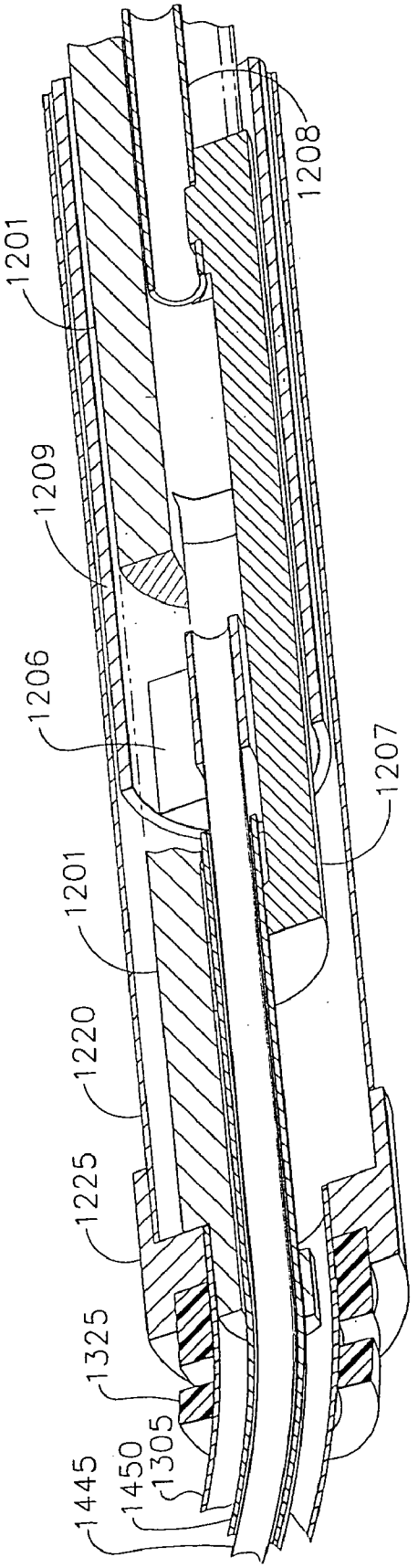

FIG. 72

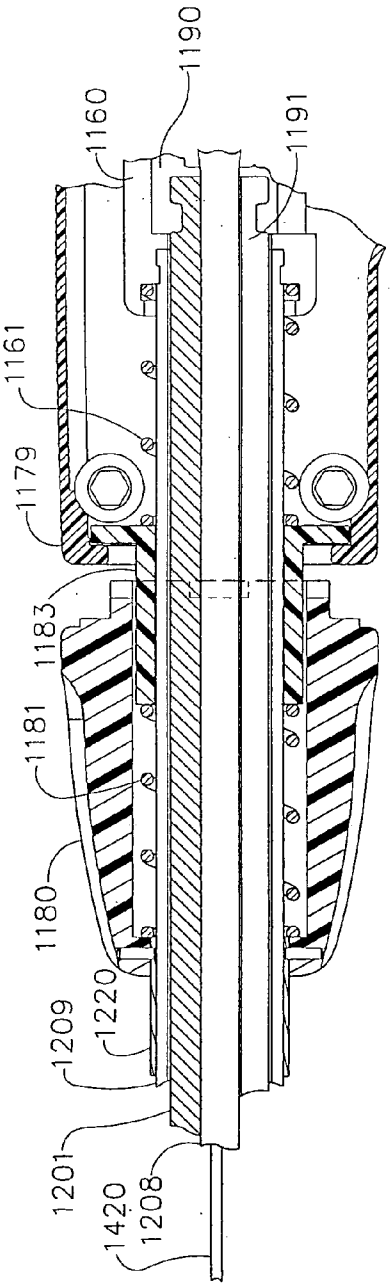
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FIG. 73

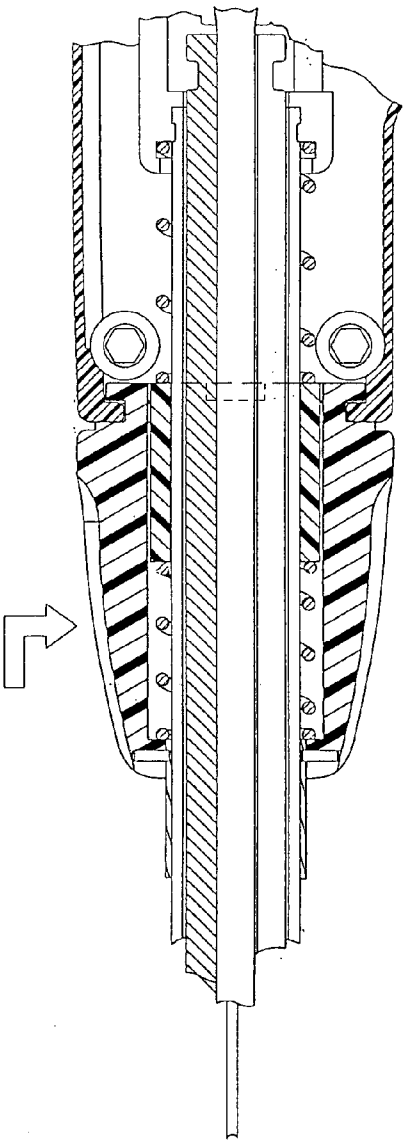

FIG. 74

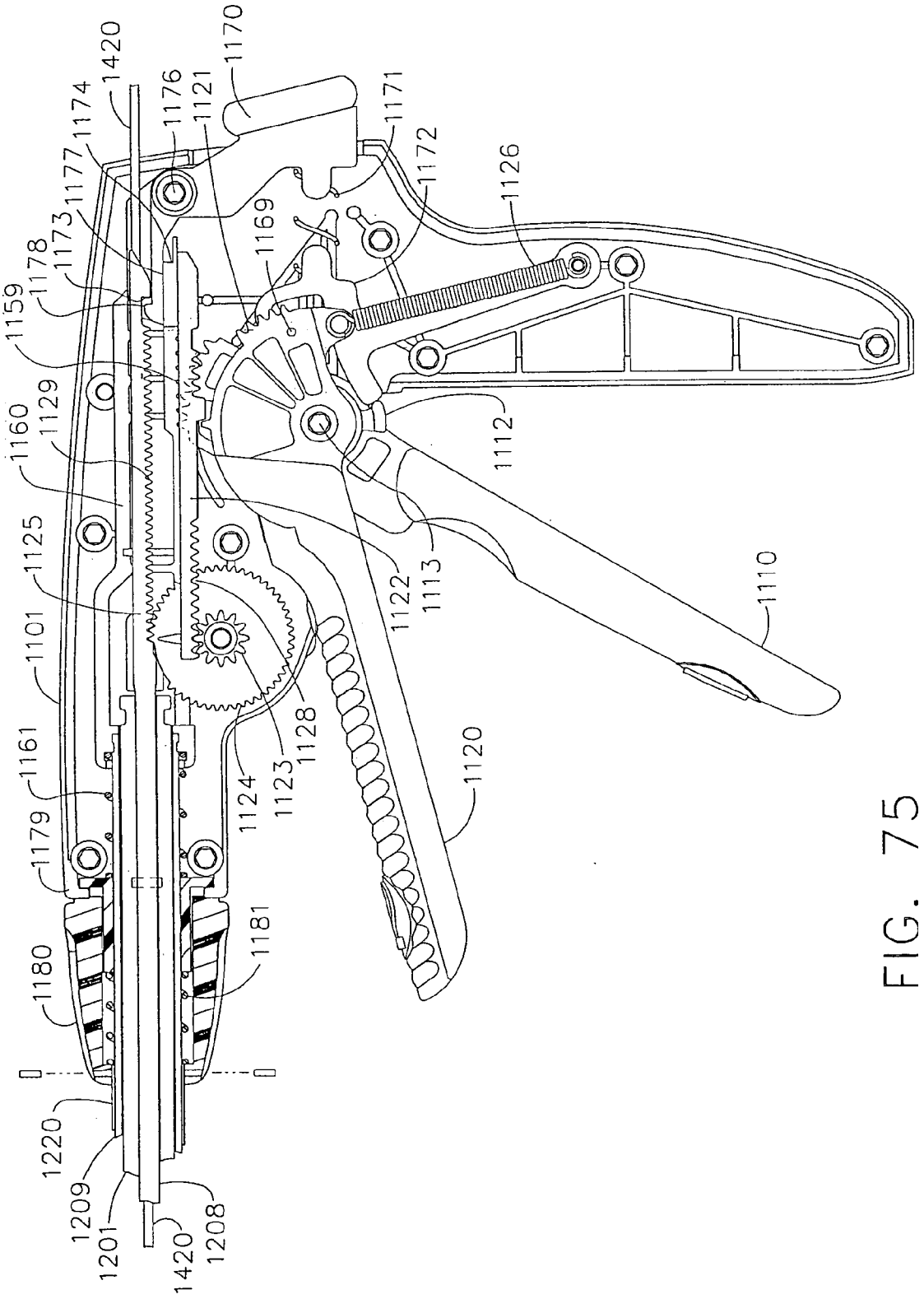
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FIG. 75

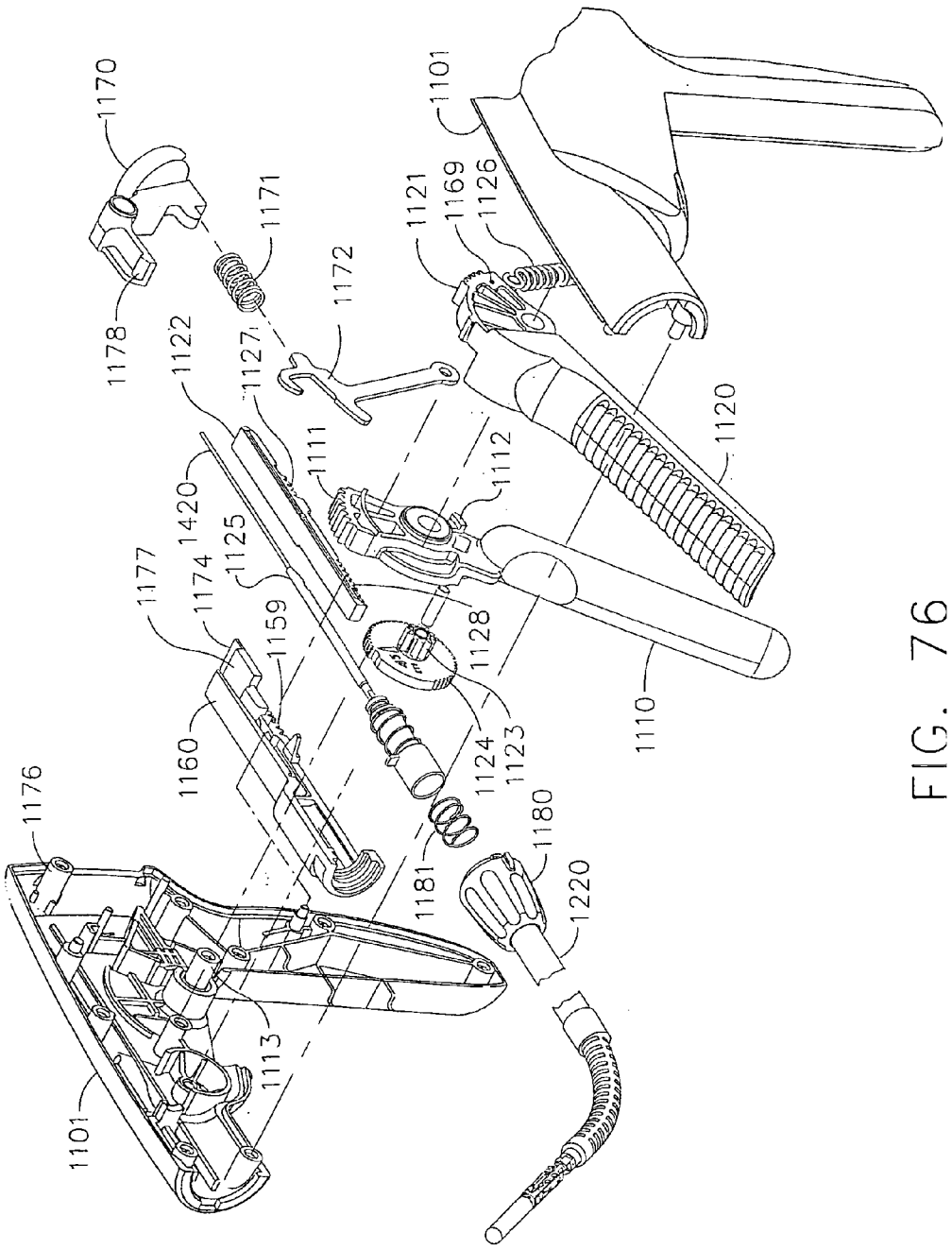
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FIG. 76

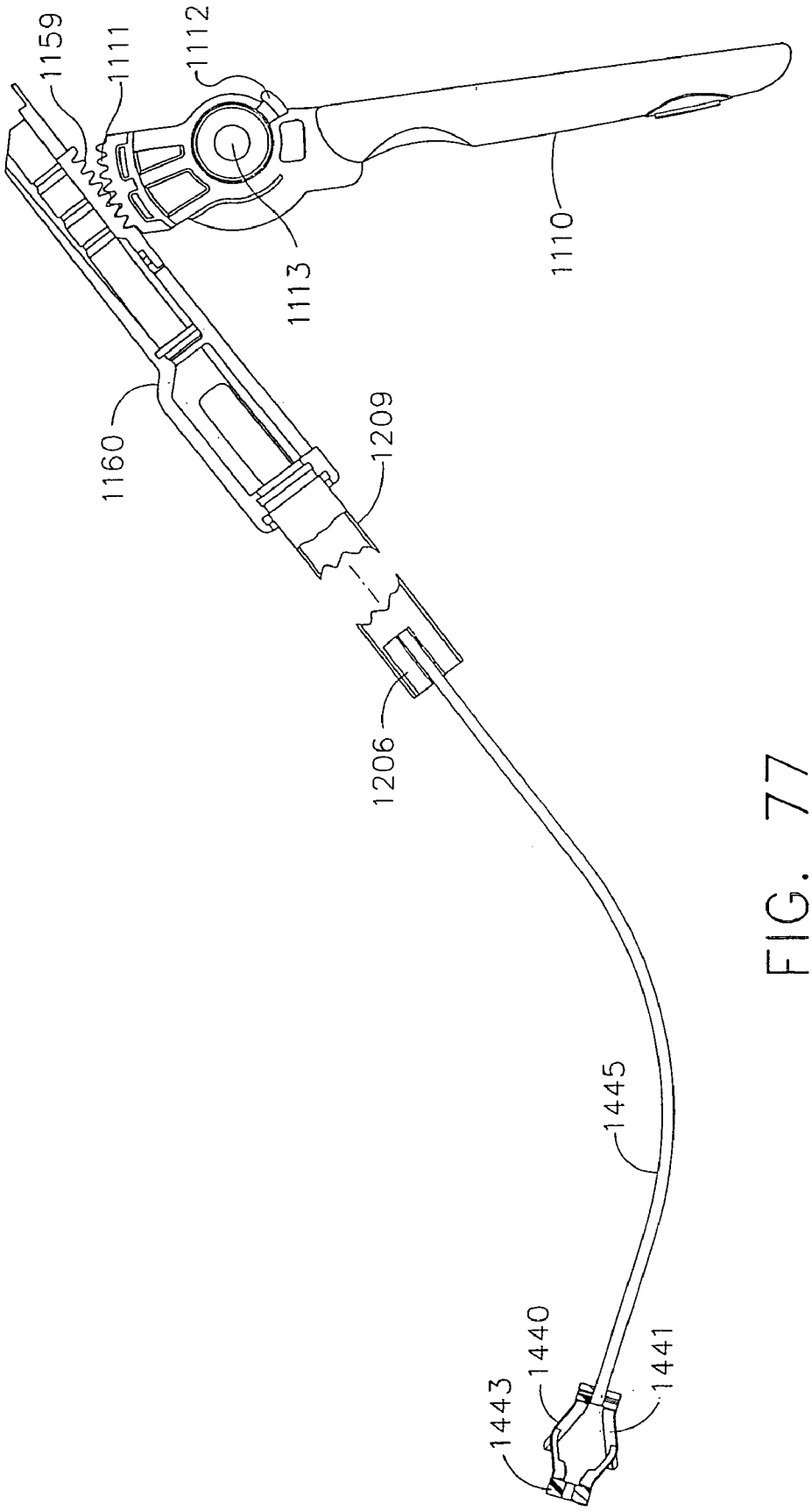

FIG. 77

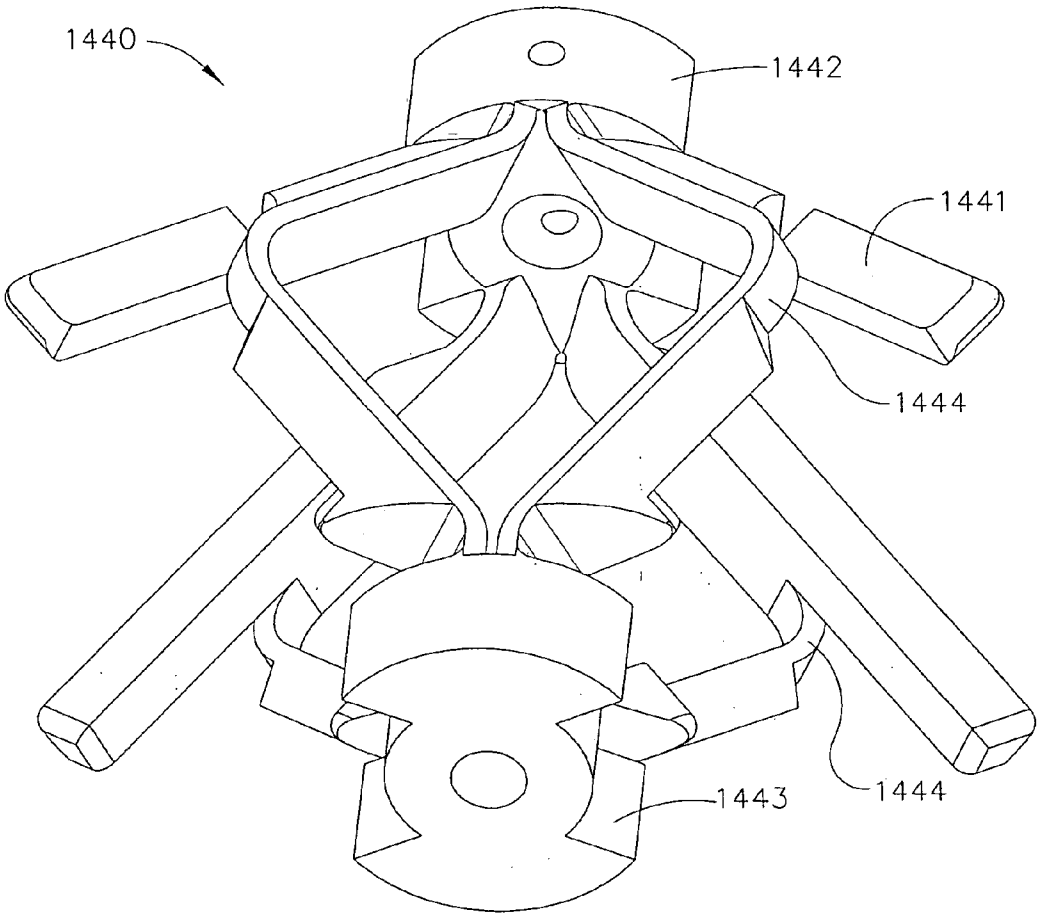

FIG. 78

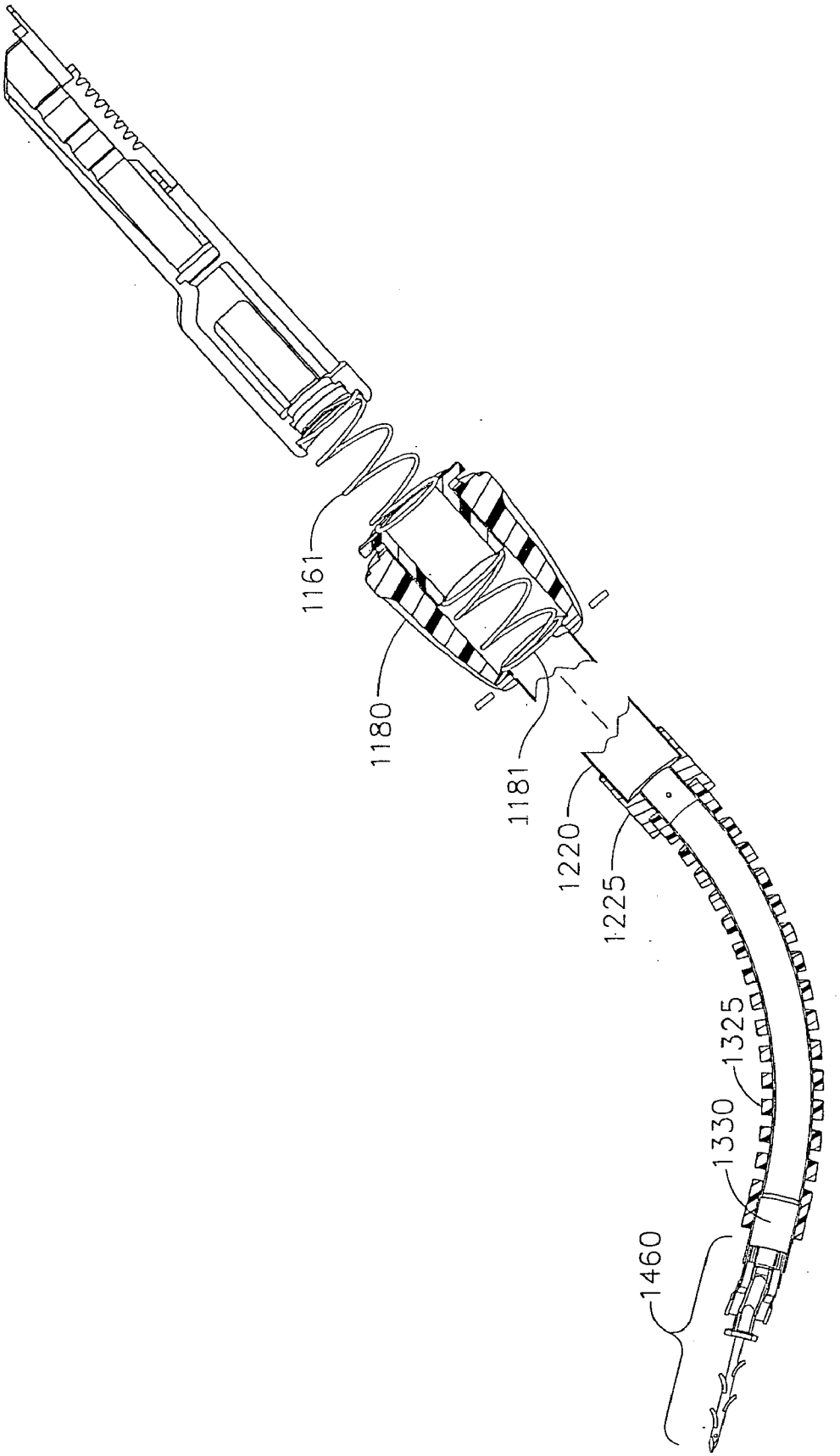

FIG. 79

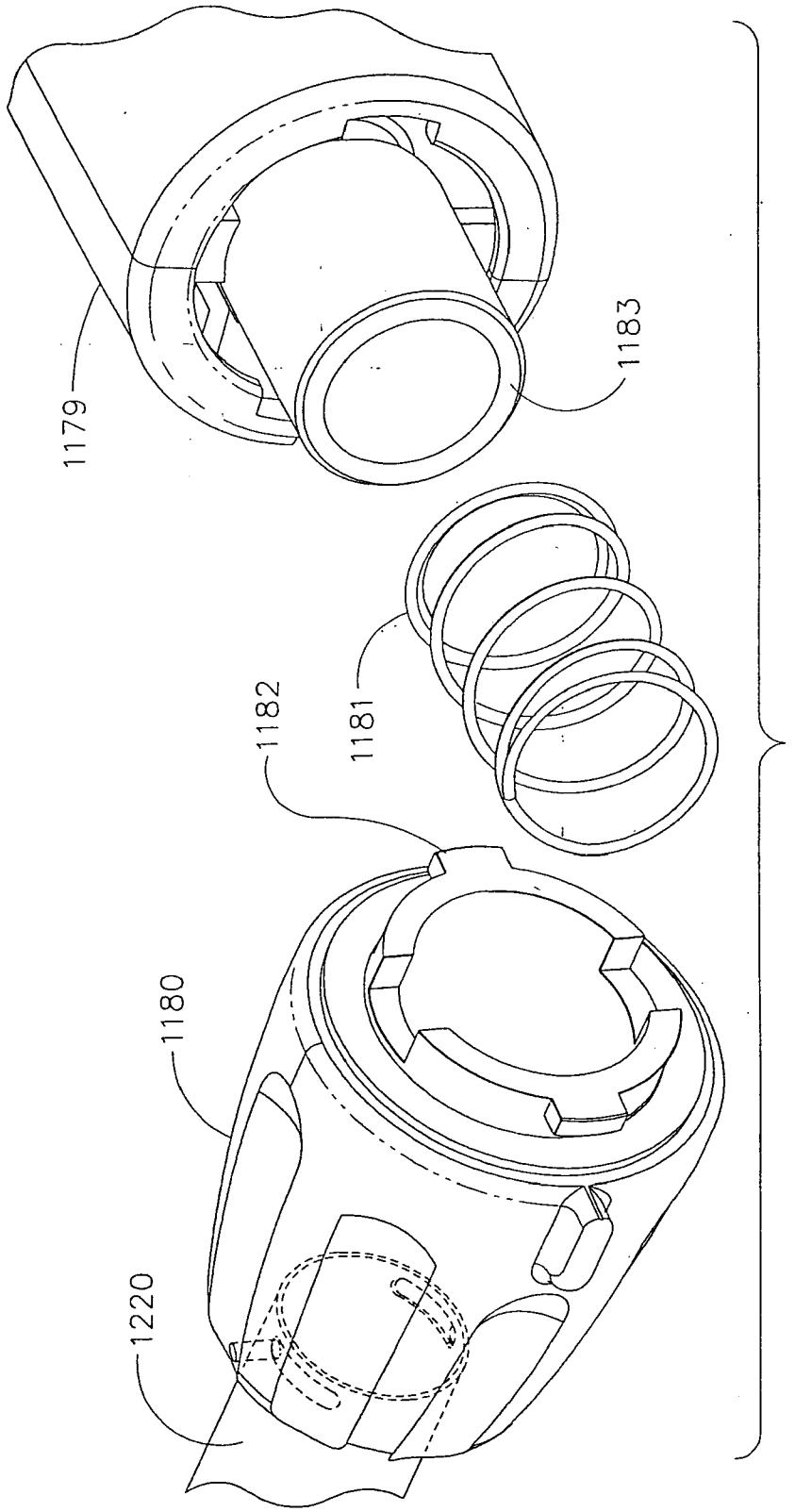

FIG. 80

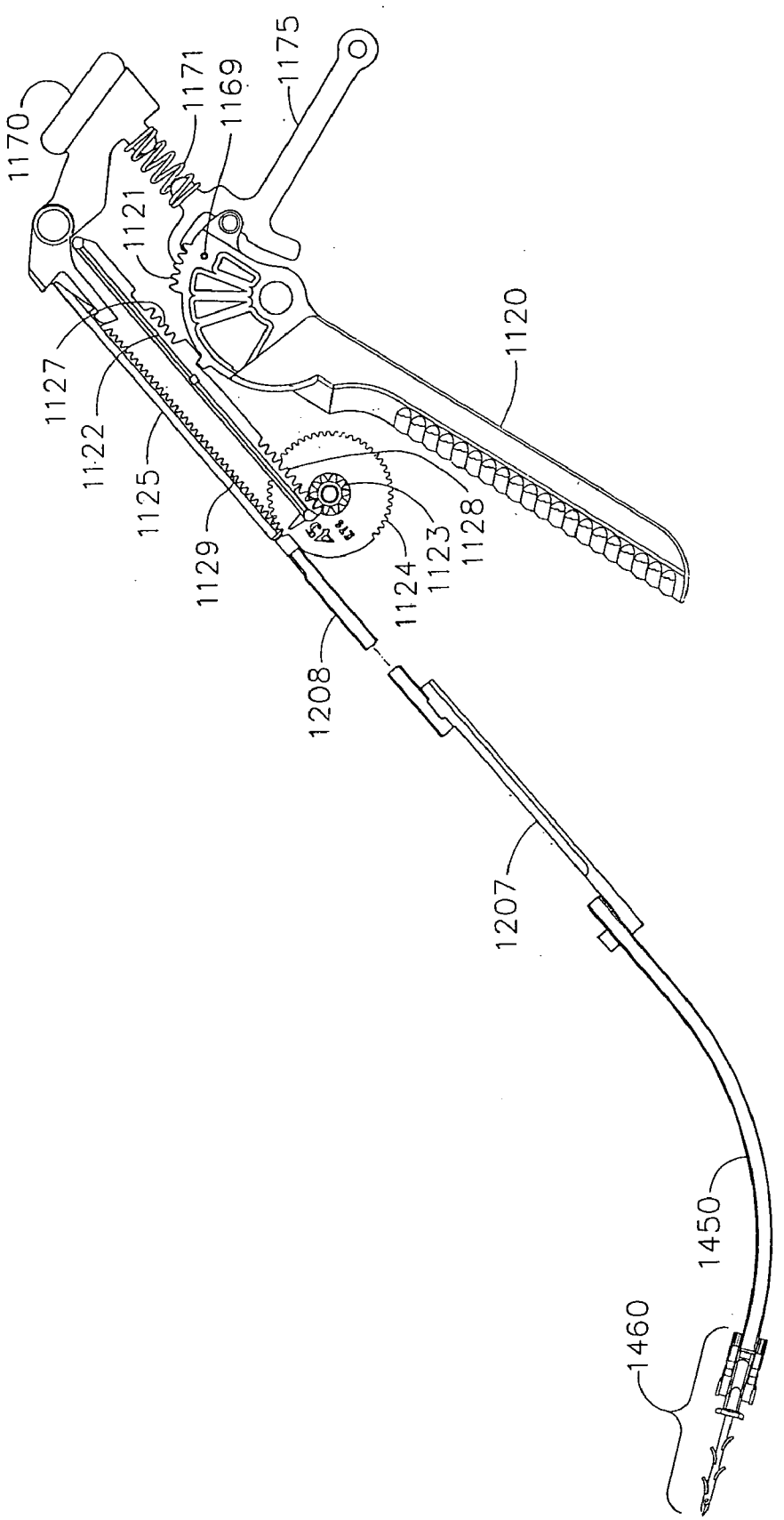
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FIG. 81

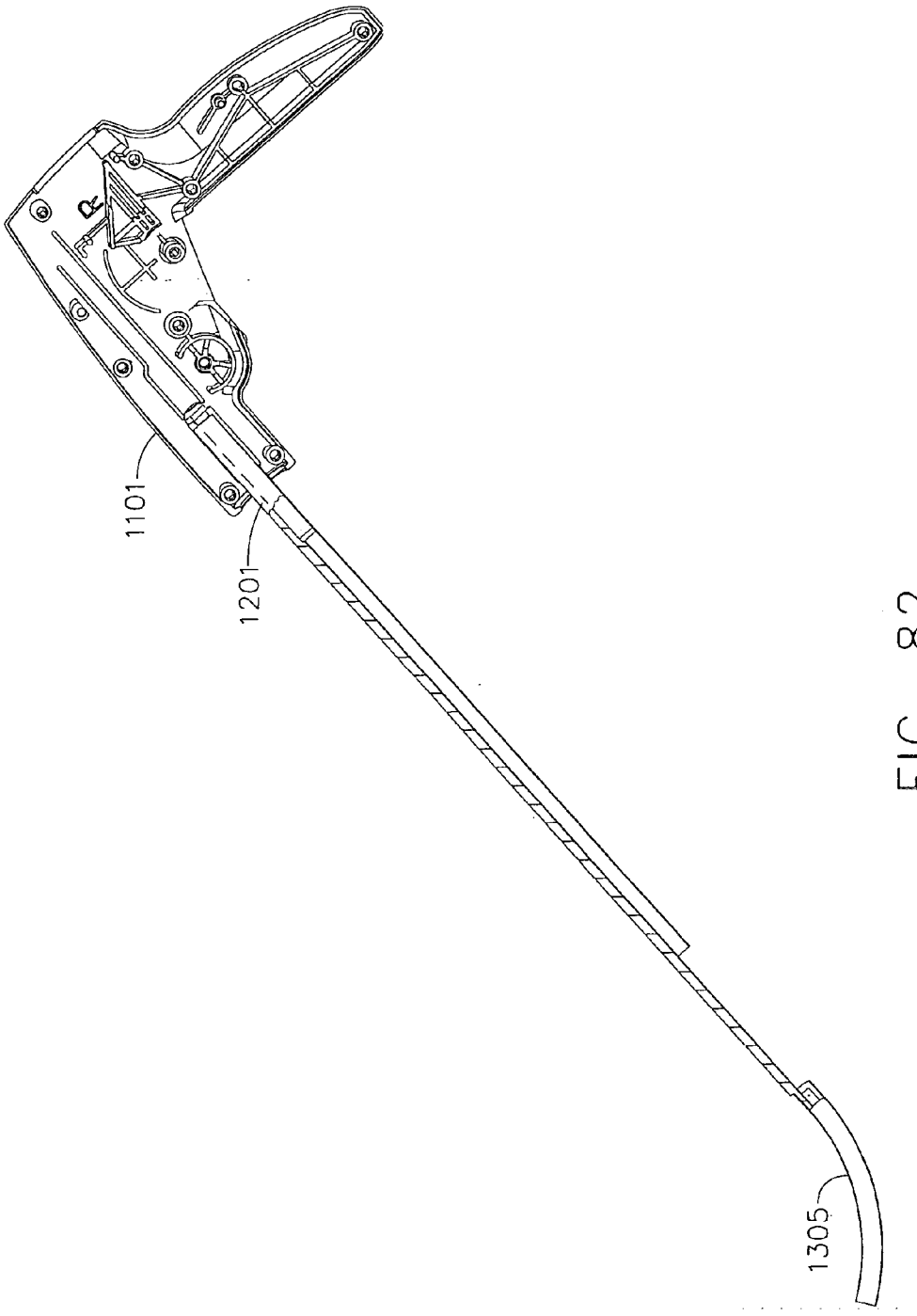

FIG. 82

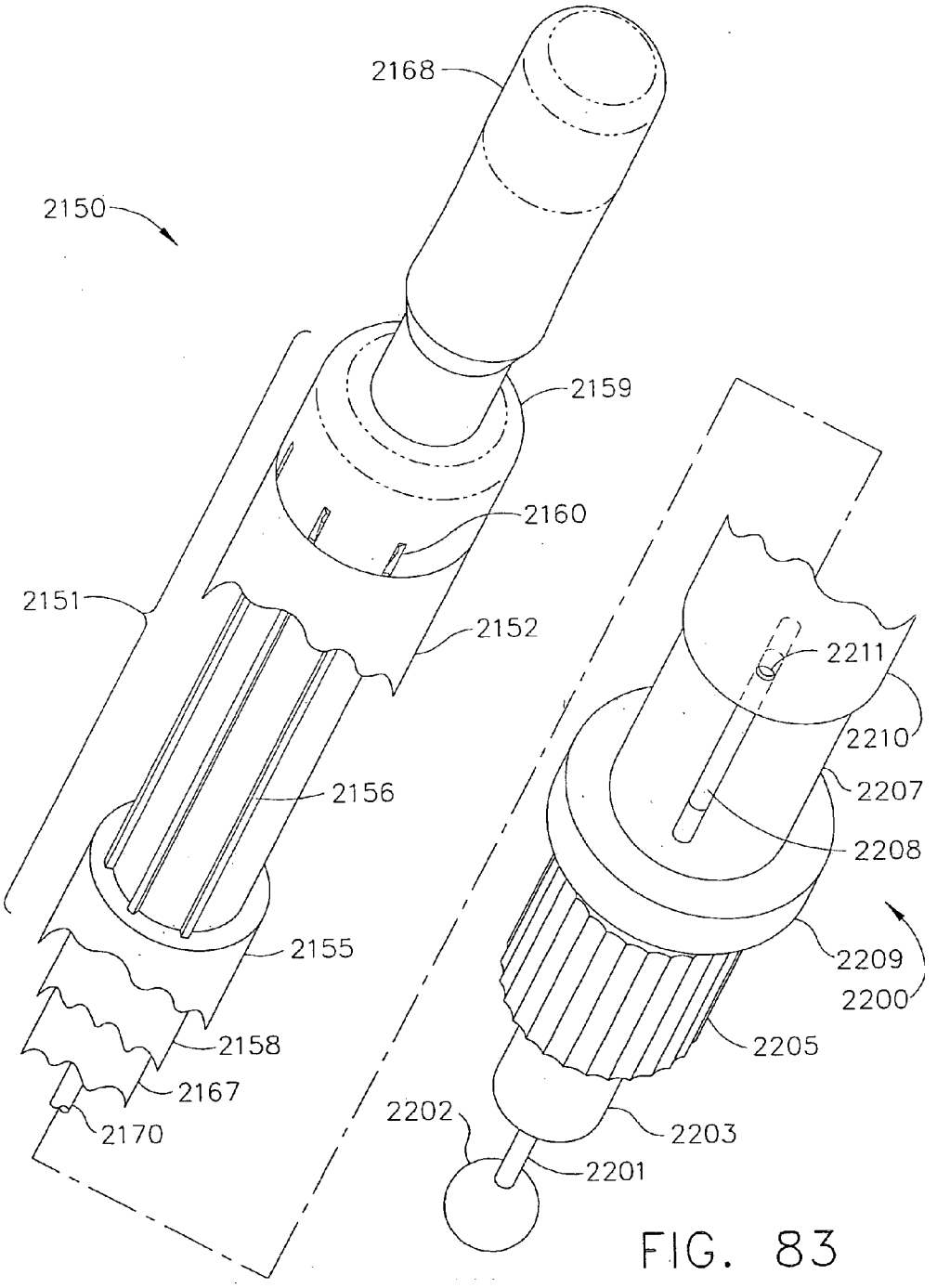
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FIG. 83

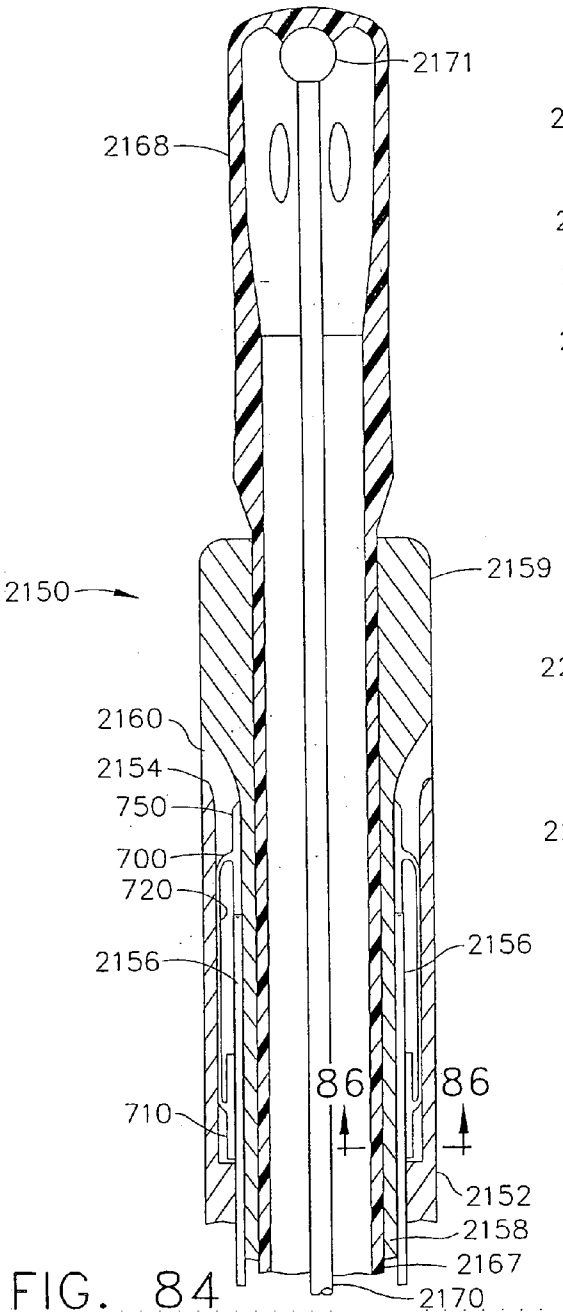
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FIG. 84

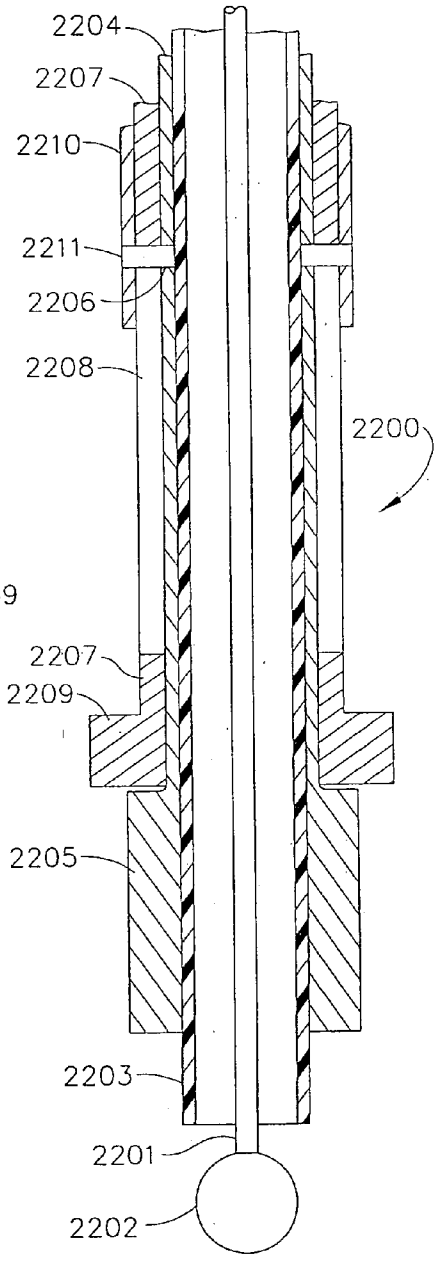
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FIG. 85

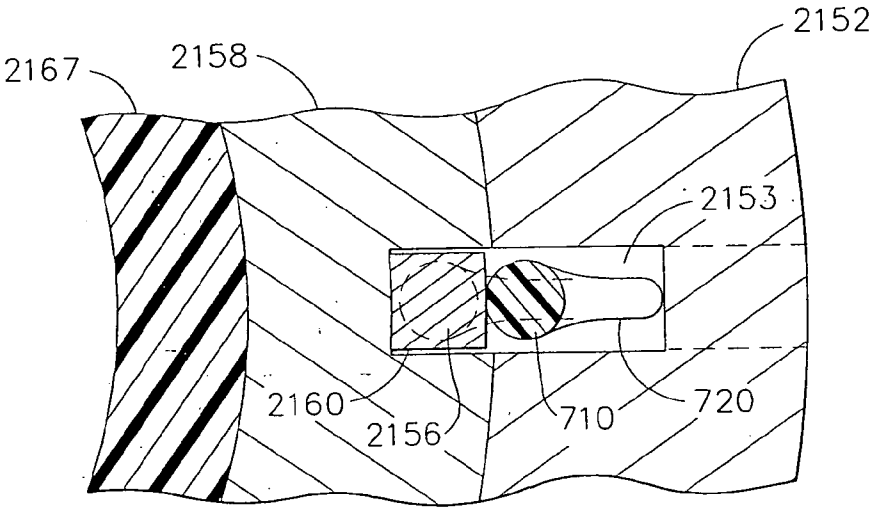
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FIG. 86

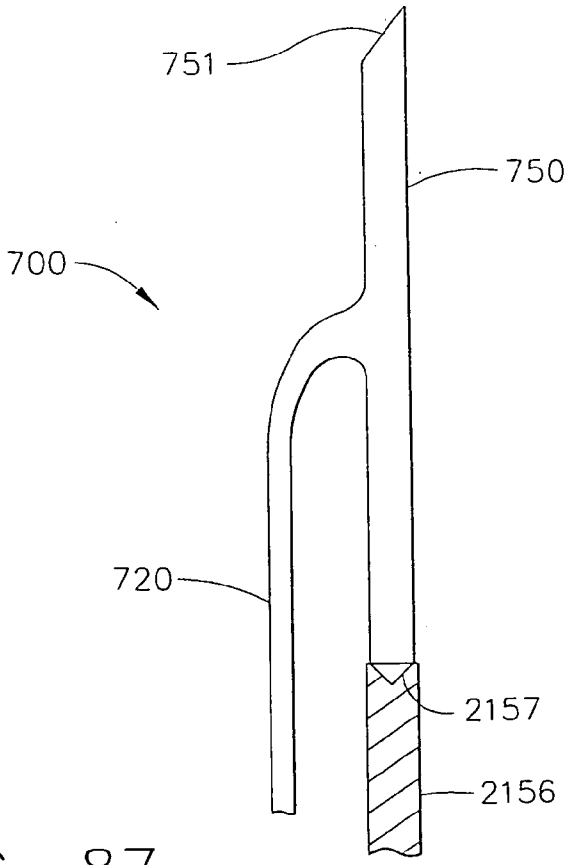
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FIG. 87

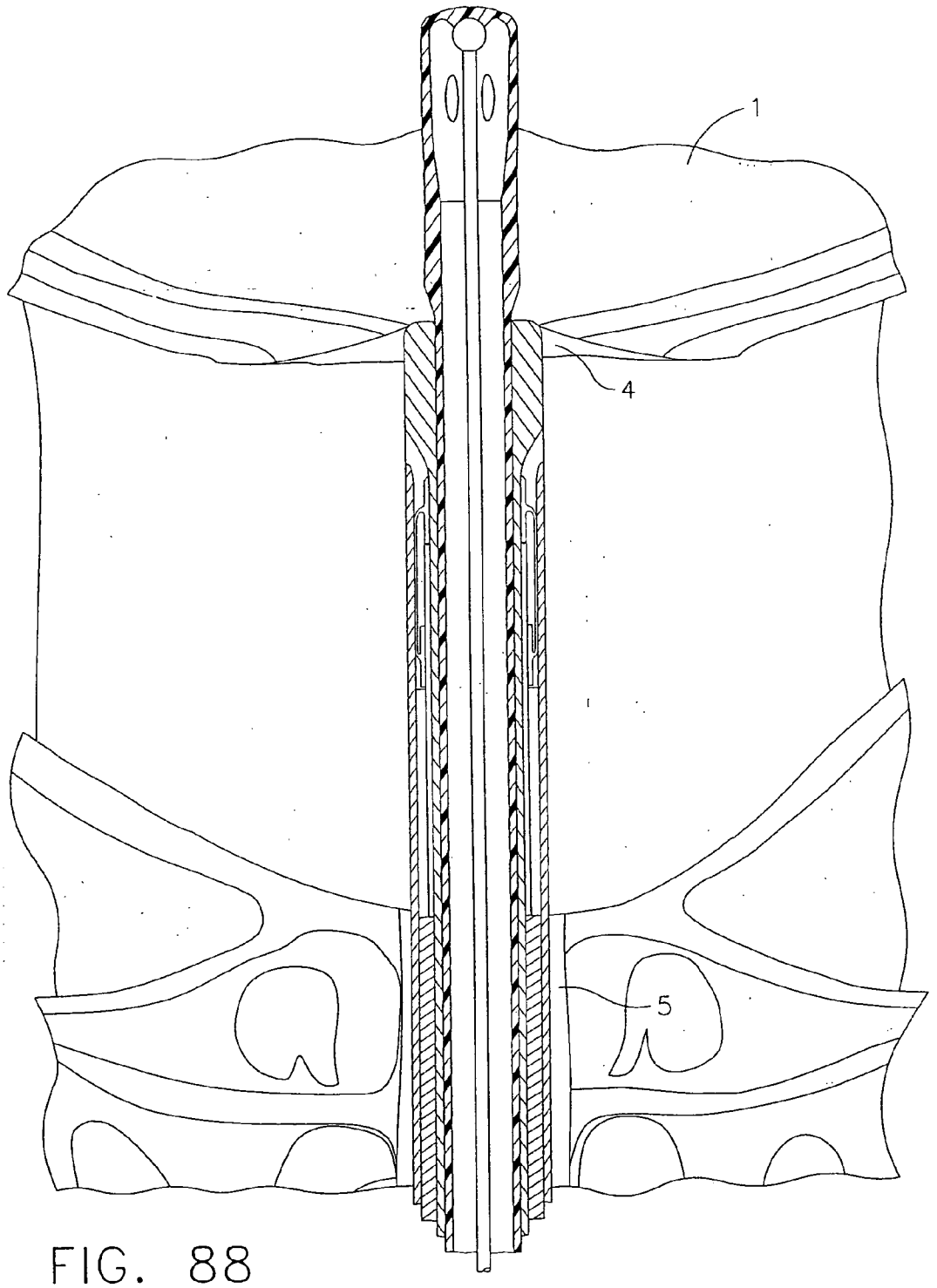

FIG. 88

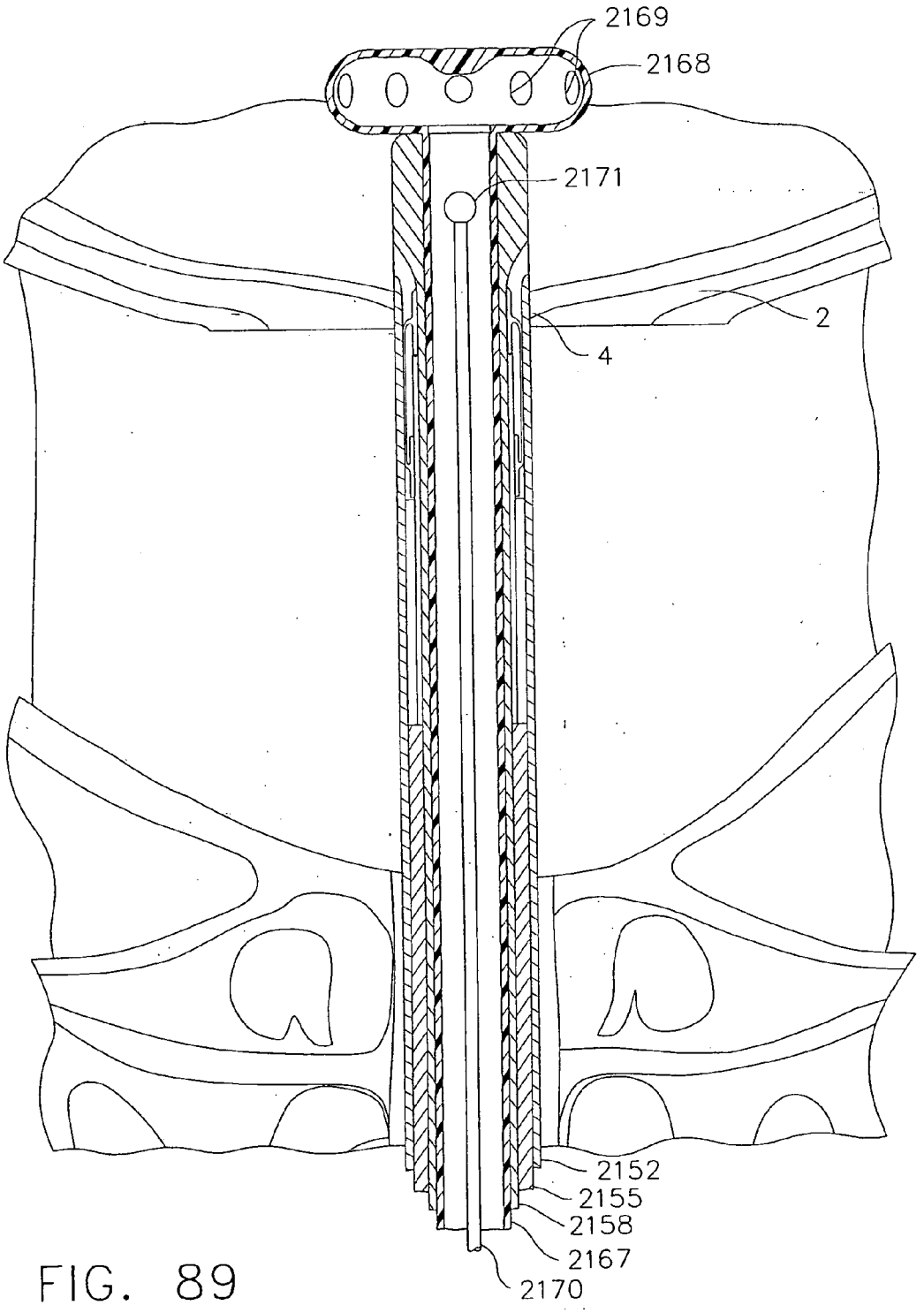

FIG. 89

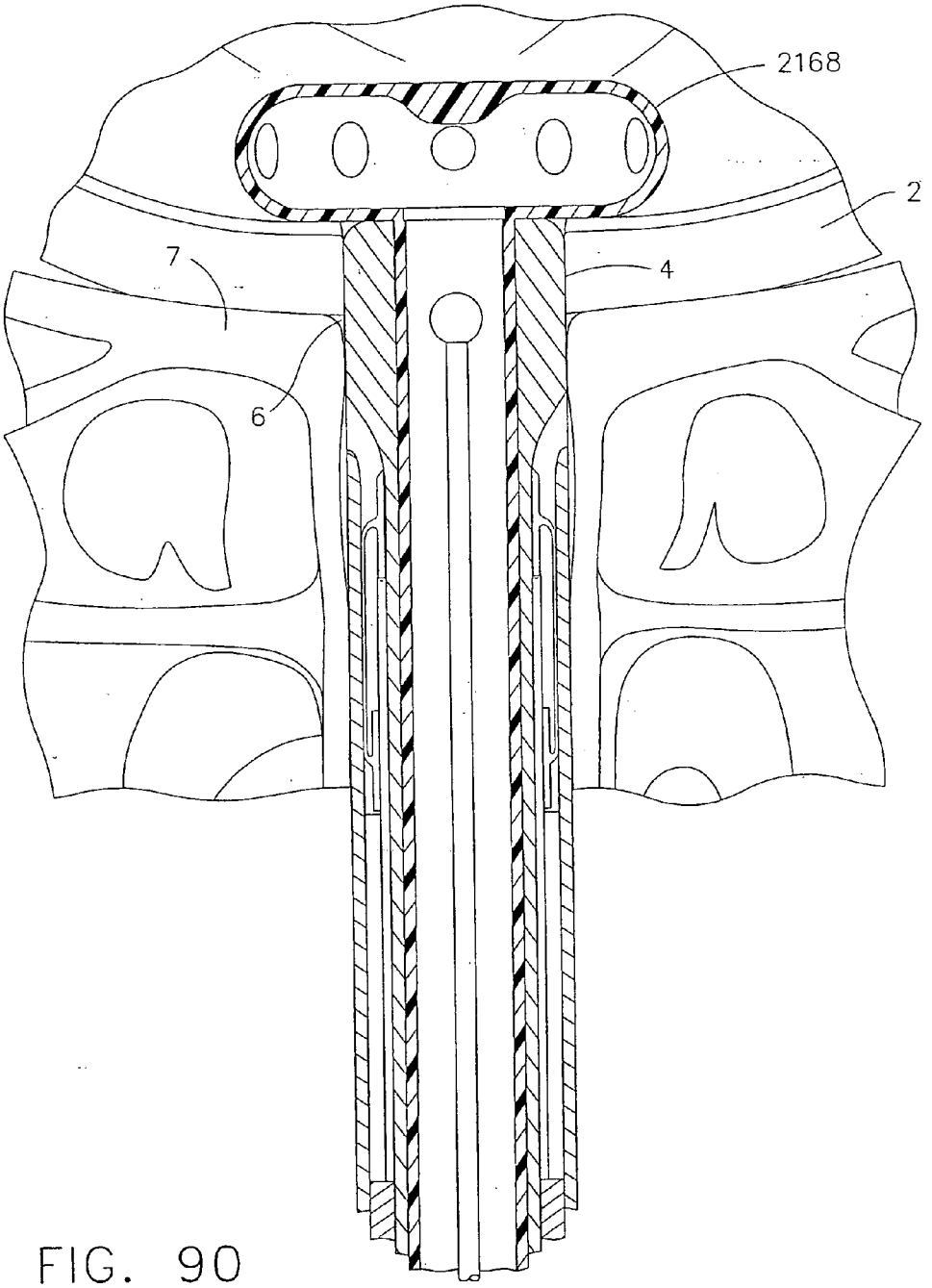

FIG. 90

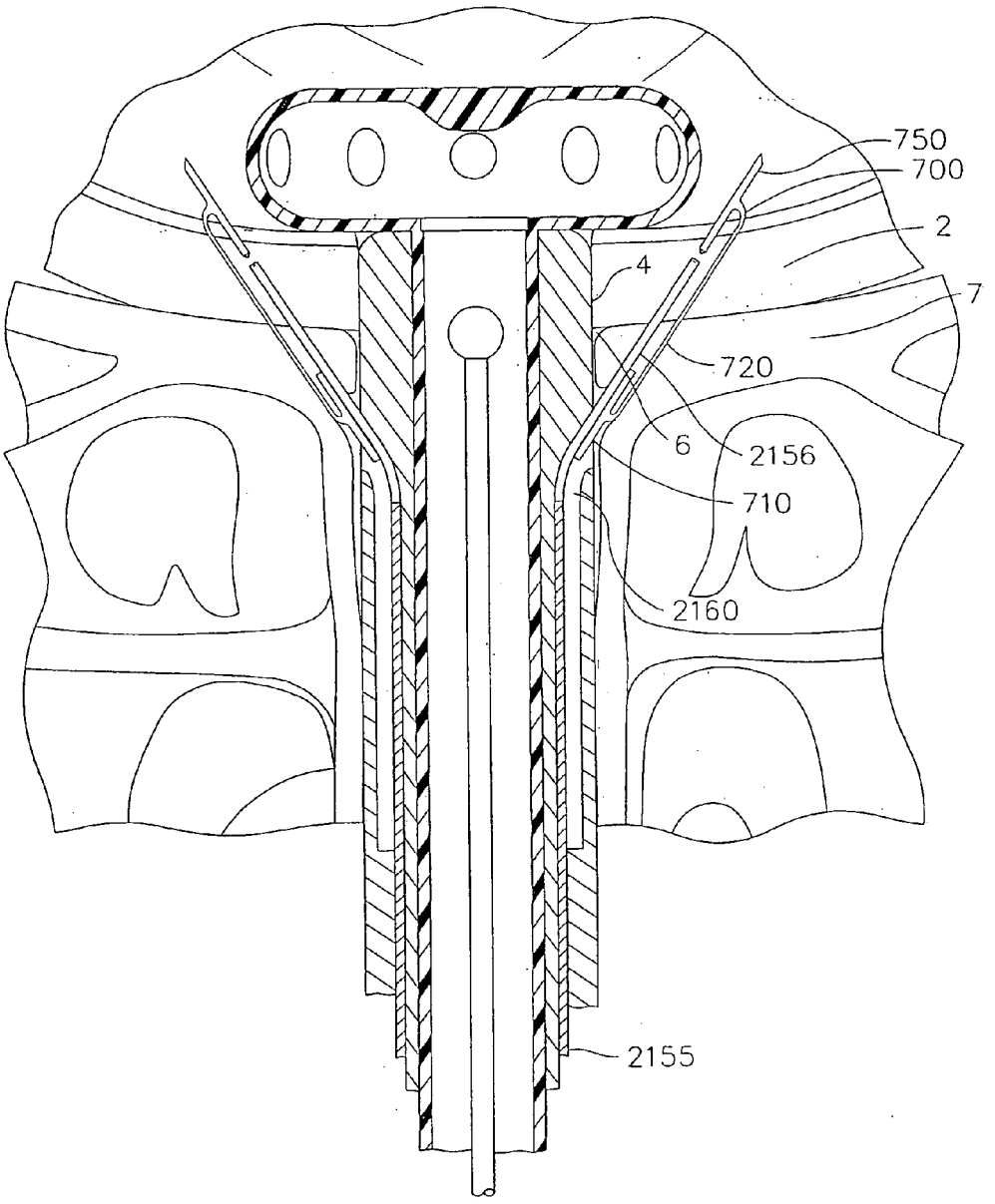

FIG. 91

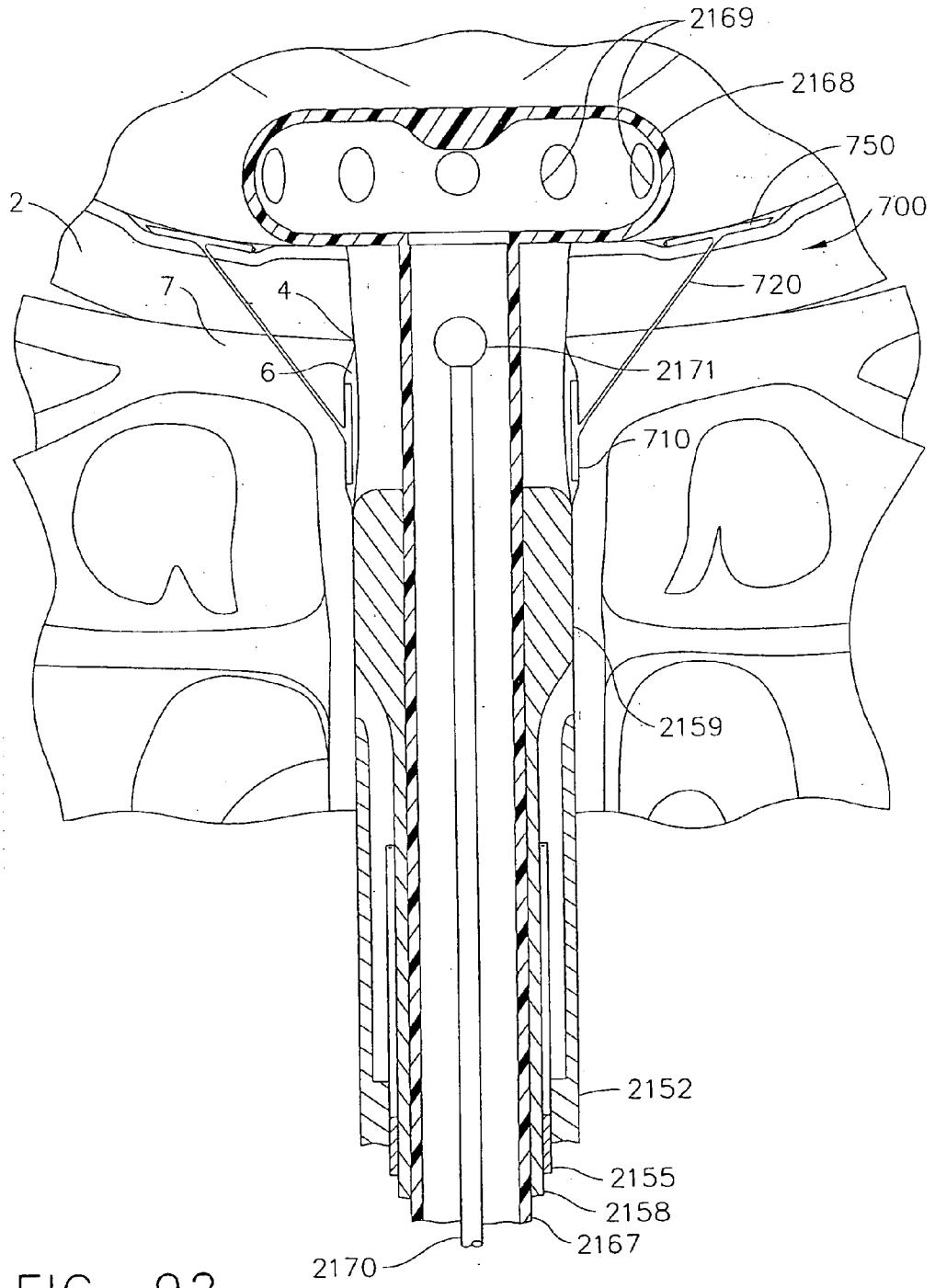
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FIG. 92

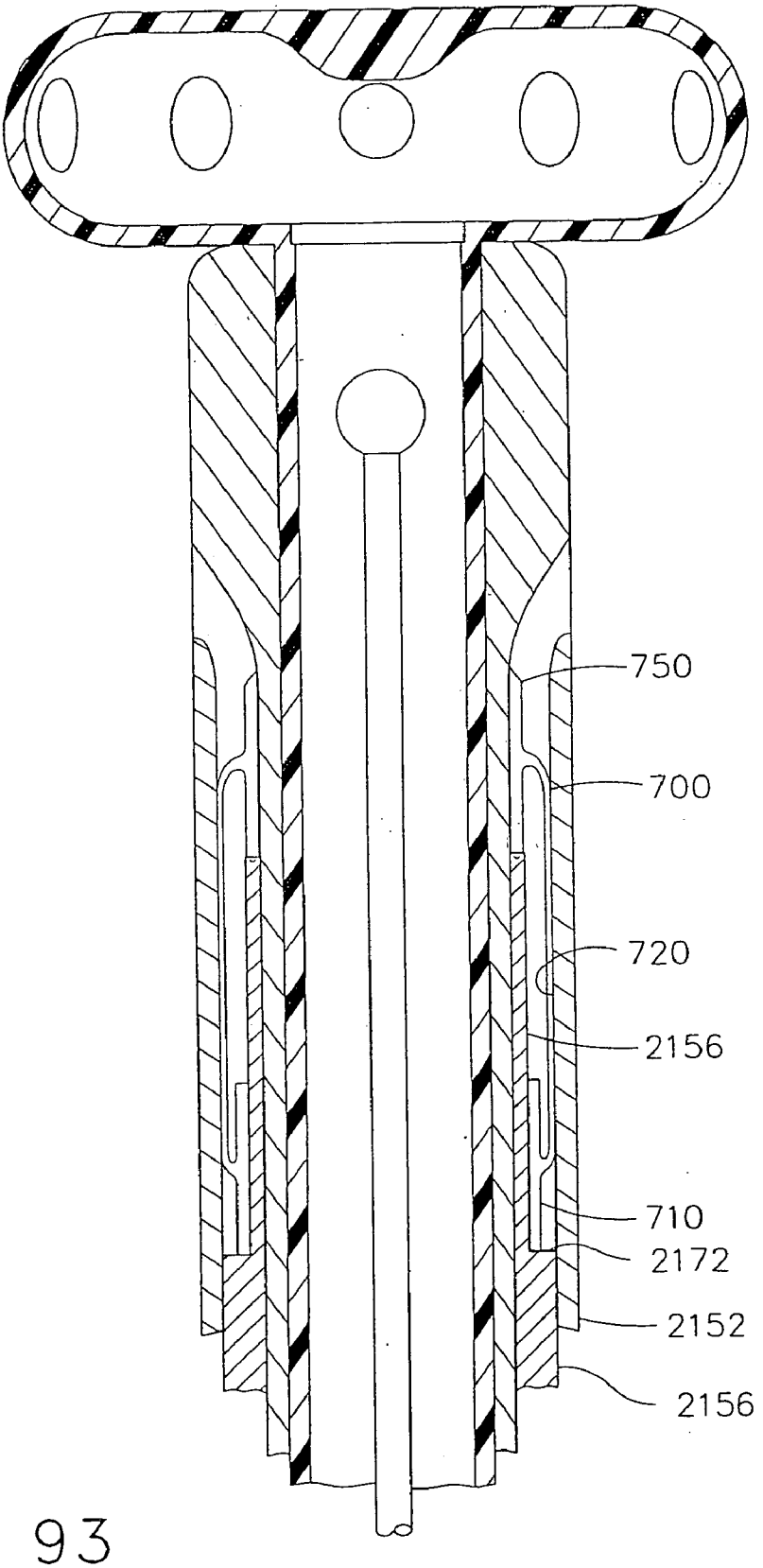

FIG. 93

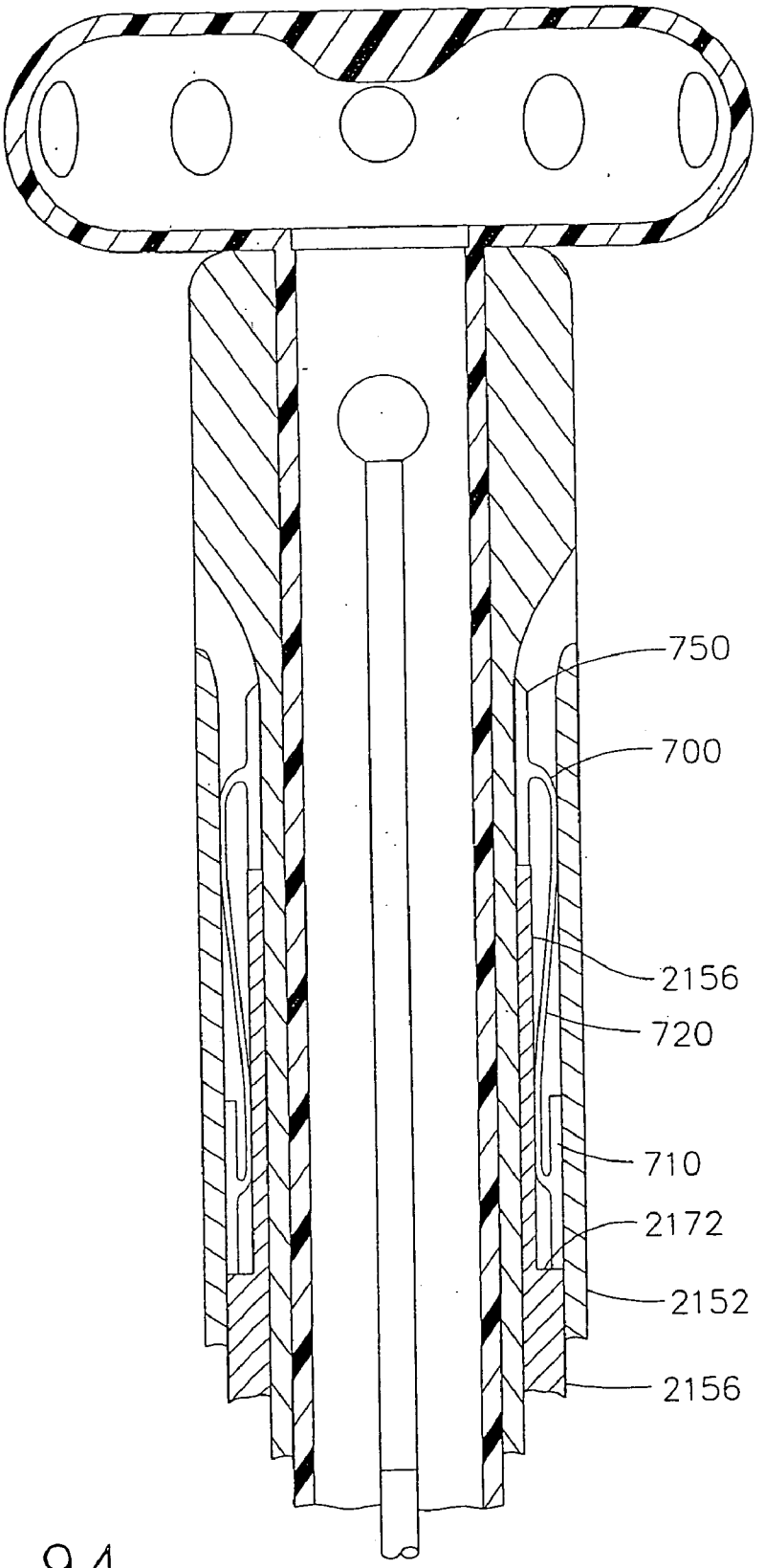

FIG. 94

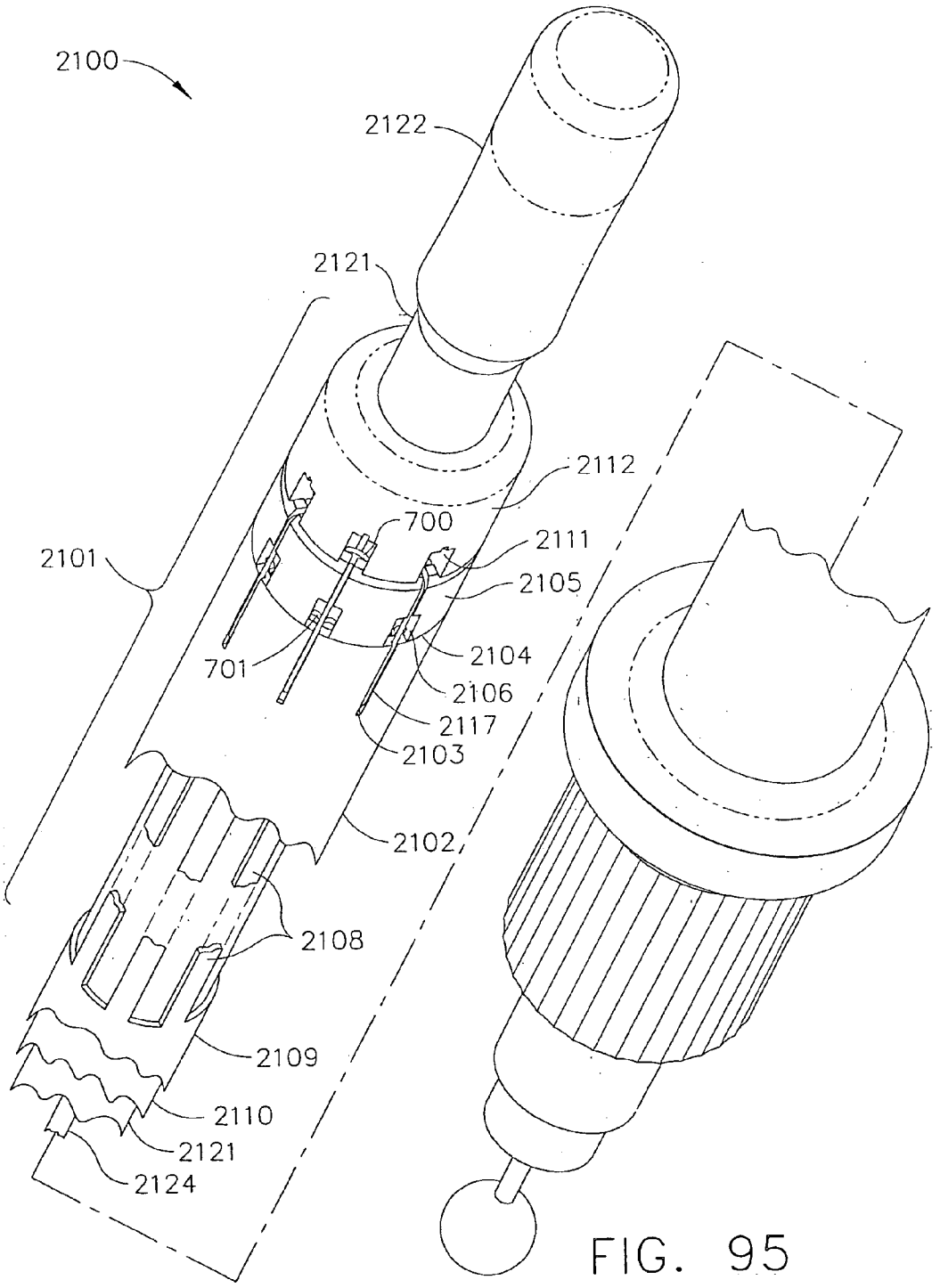
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FIG. 95

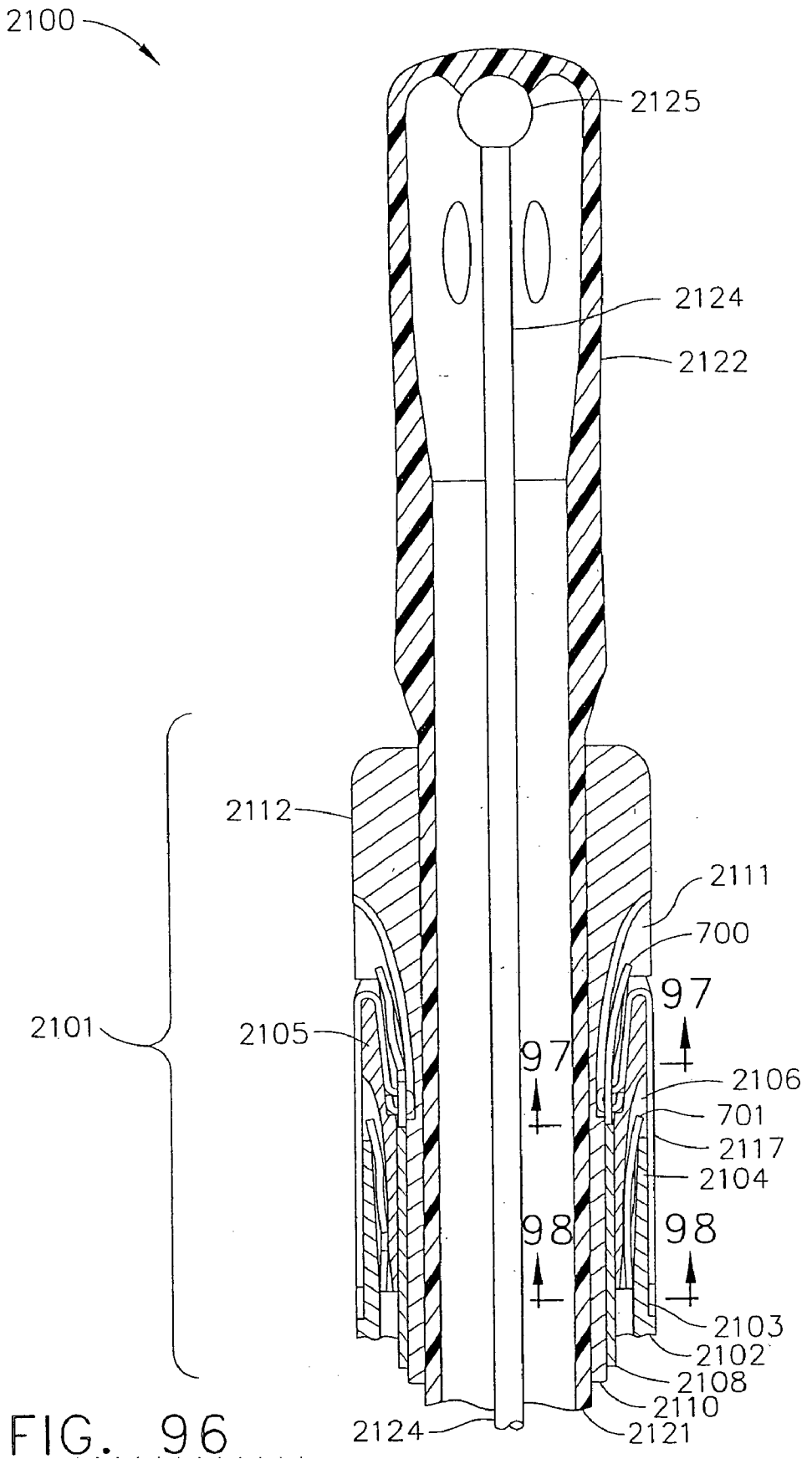
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FIG. 96

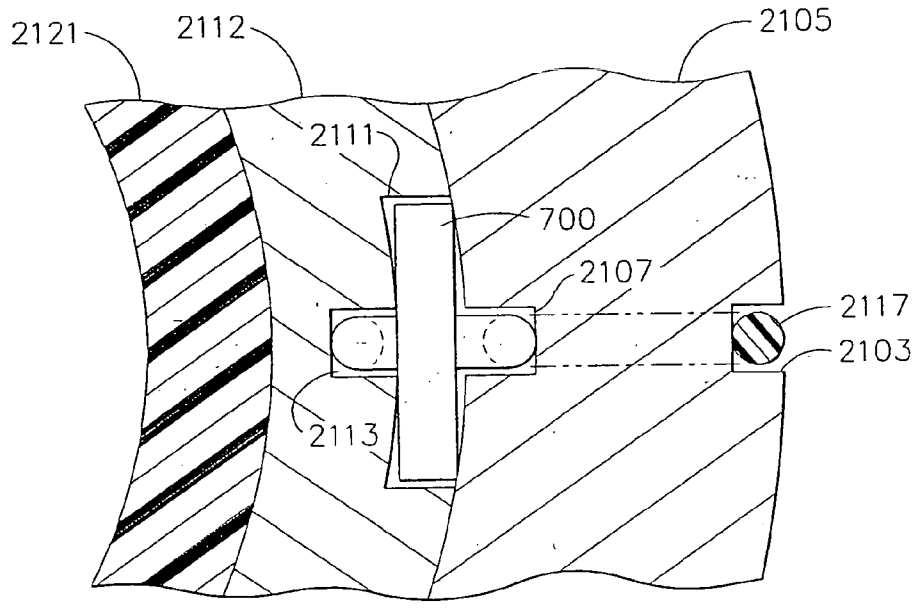
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FIG. 97

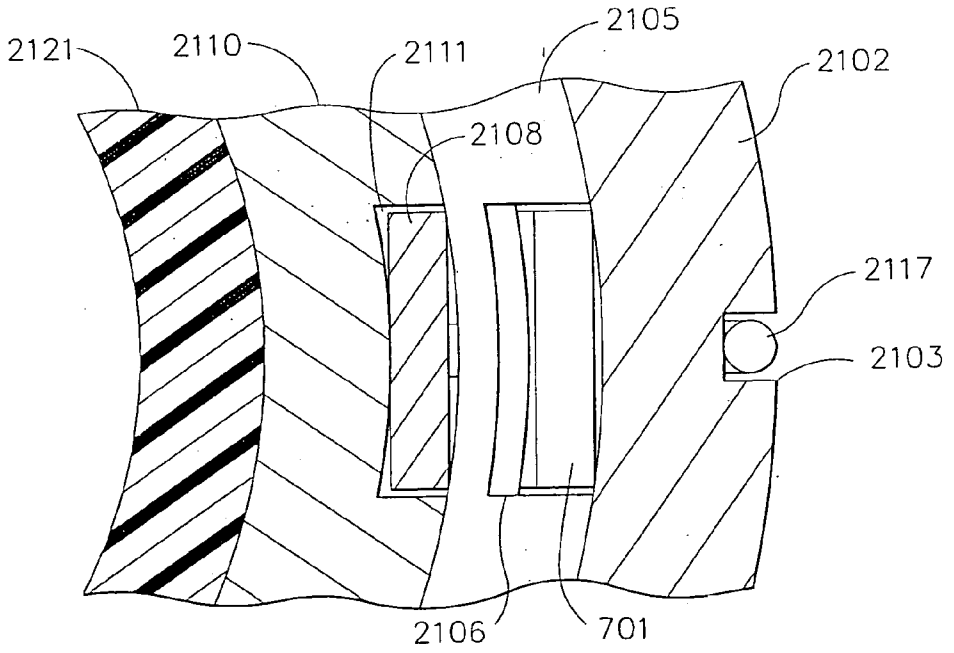
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FIG. 98

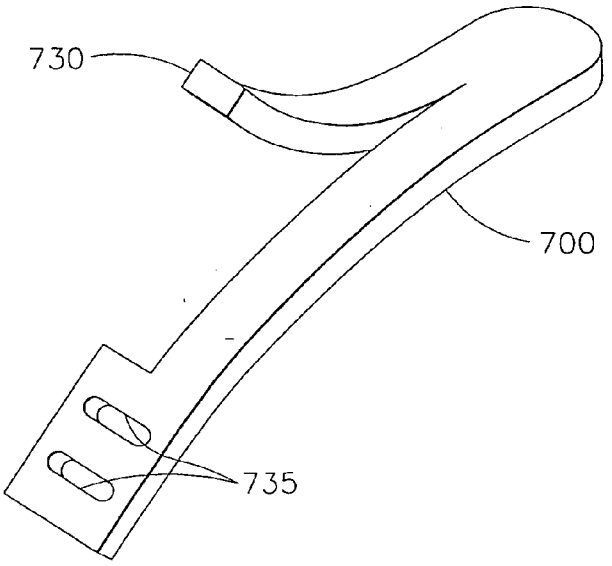

FIG. 99

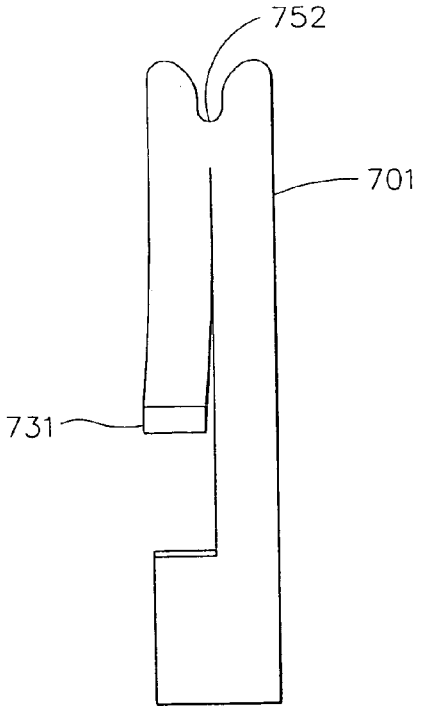

FIG. 100

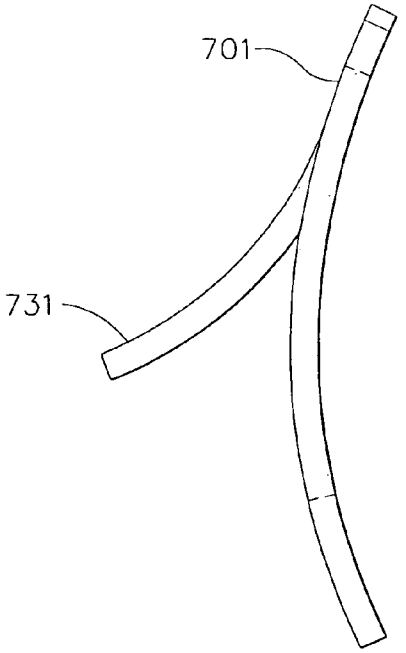

FIG. 101

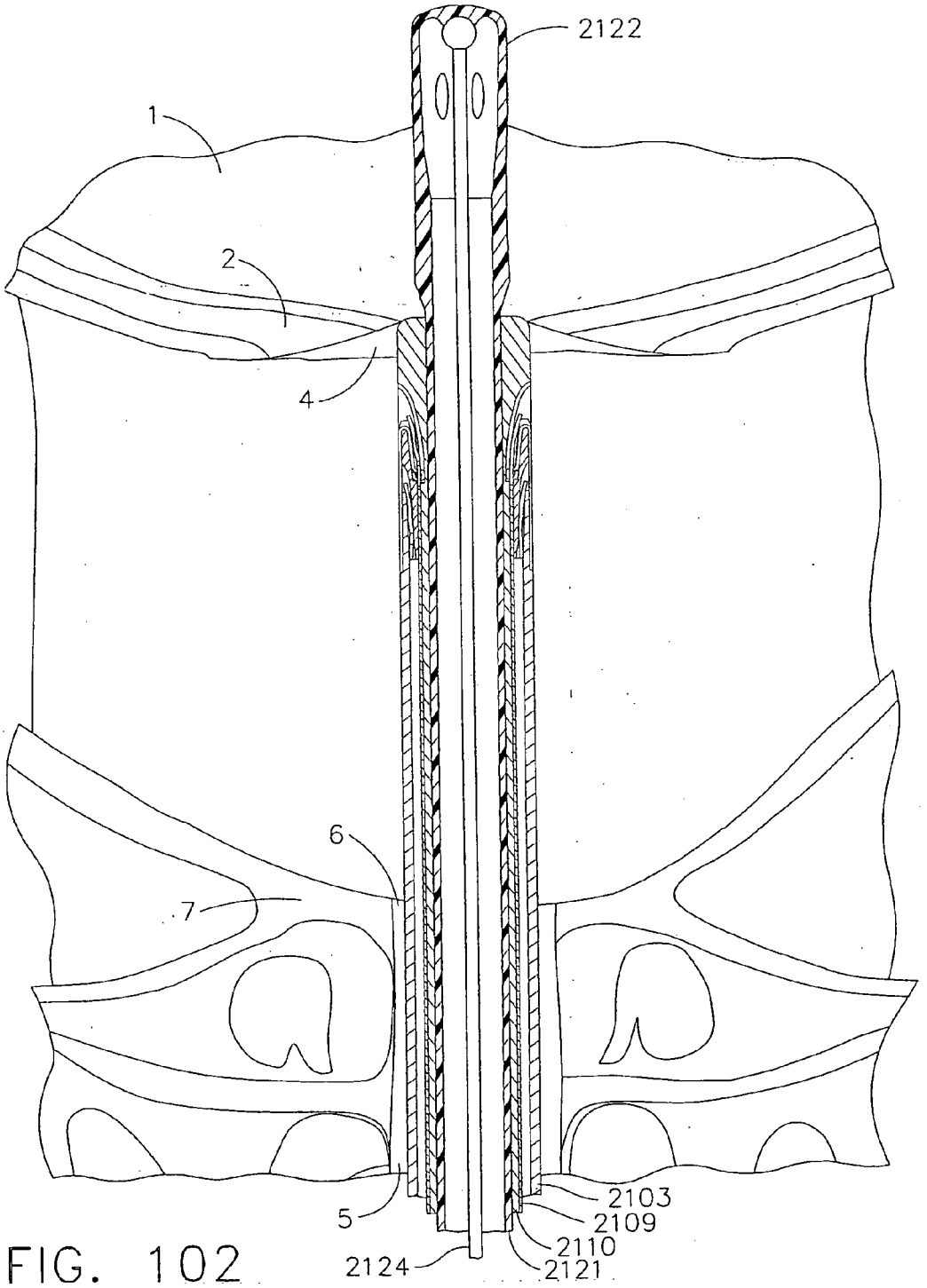

FIG. 102

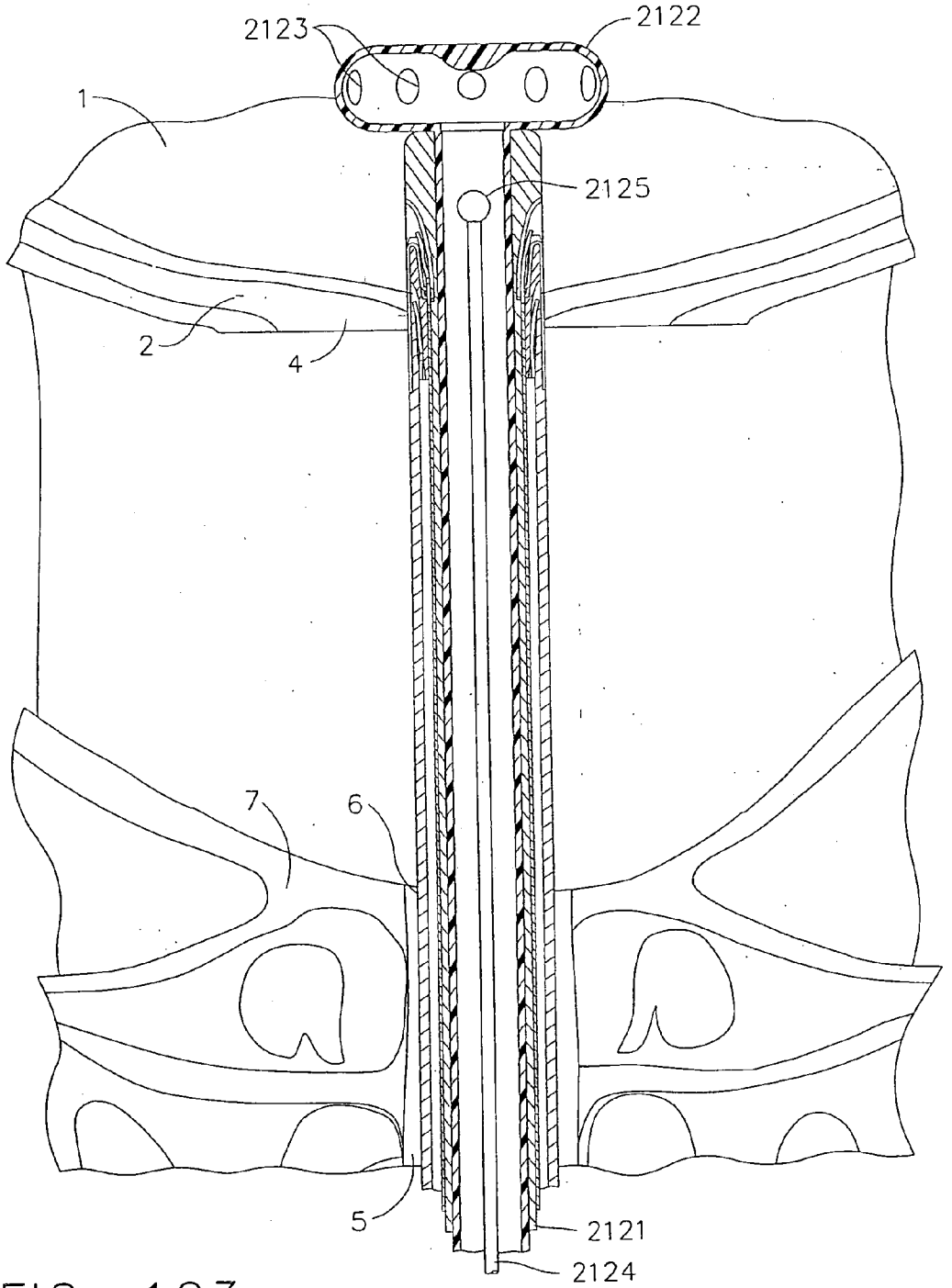

FIG. 103

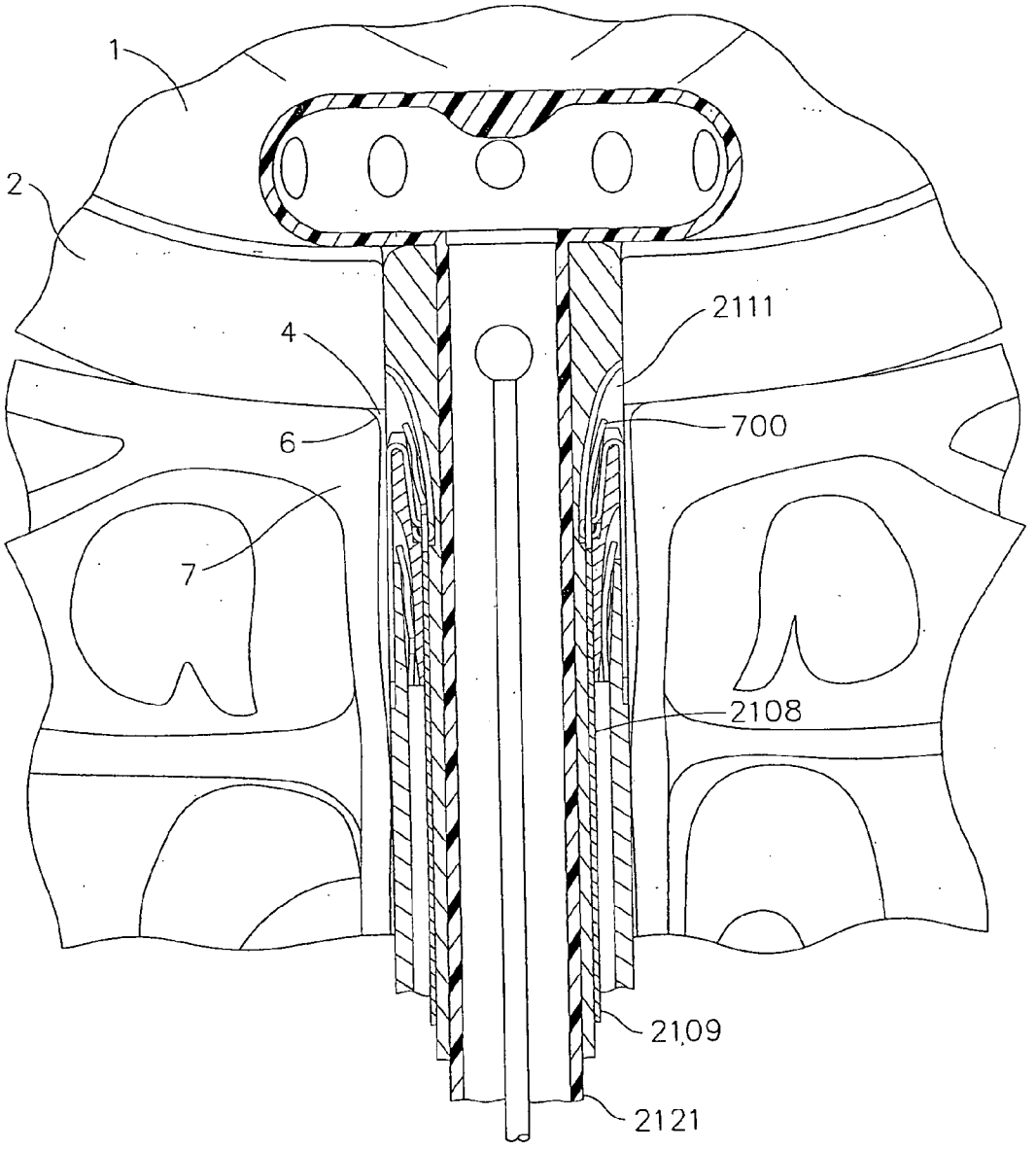

FIG. 104

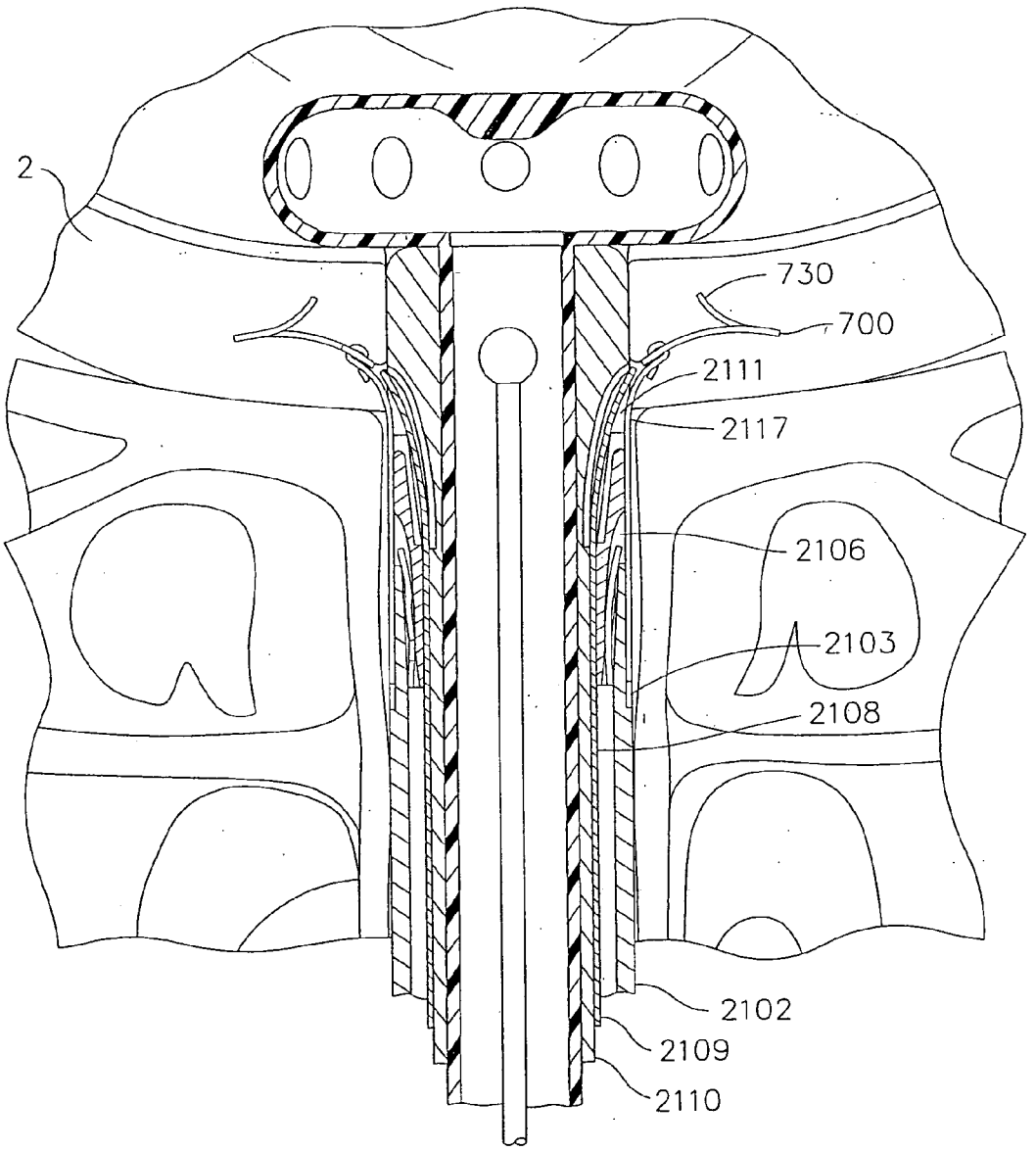

FIG. 105

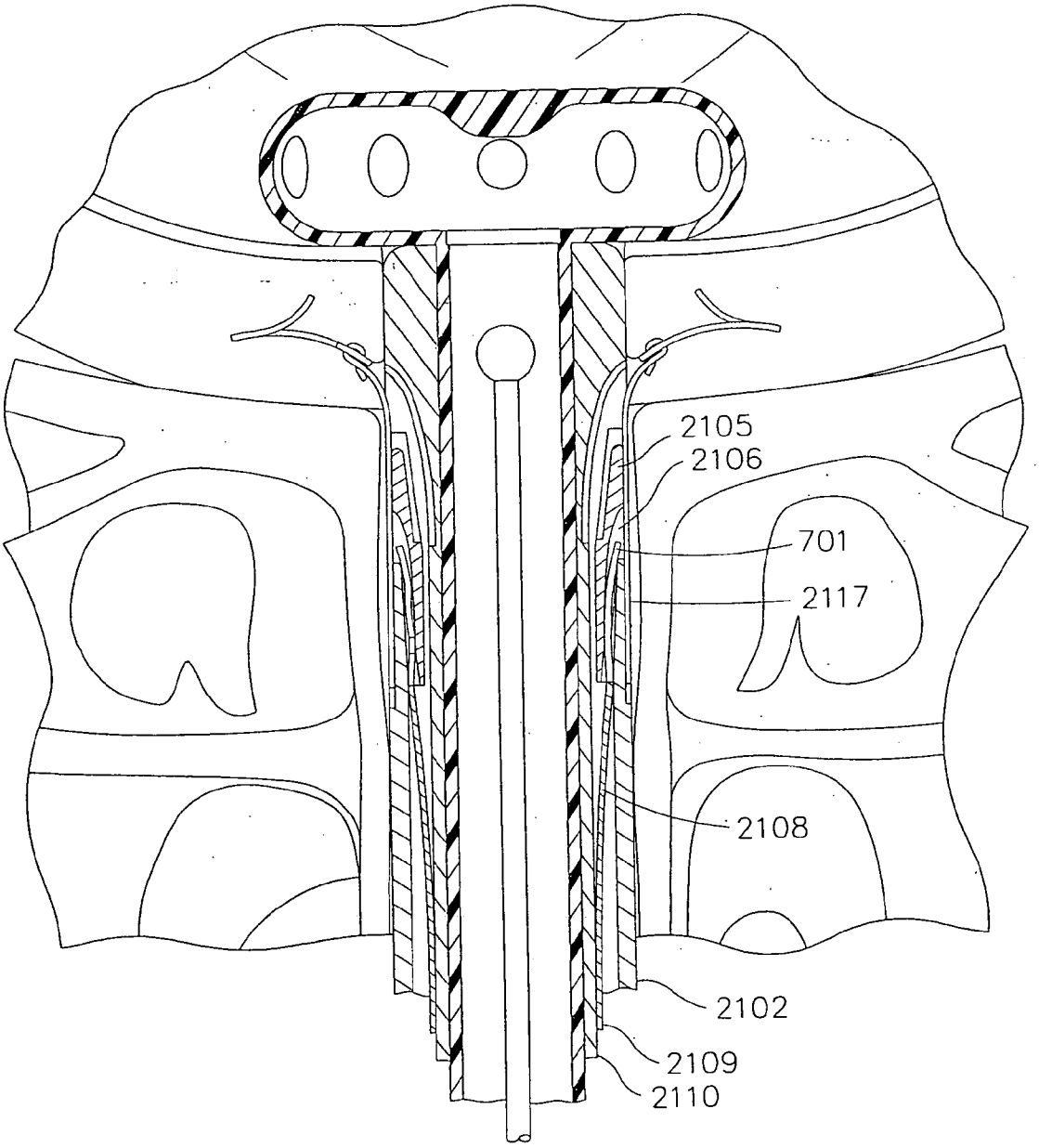

FIG. 106

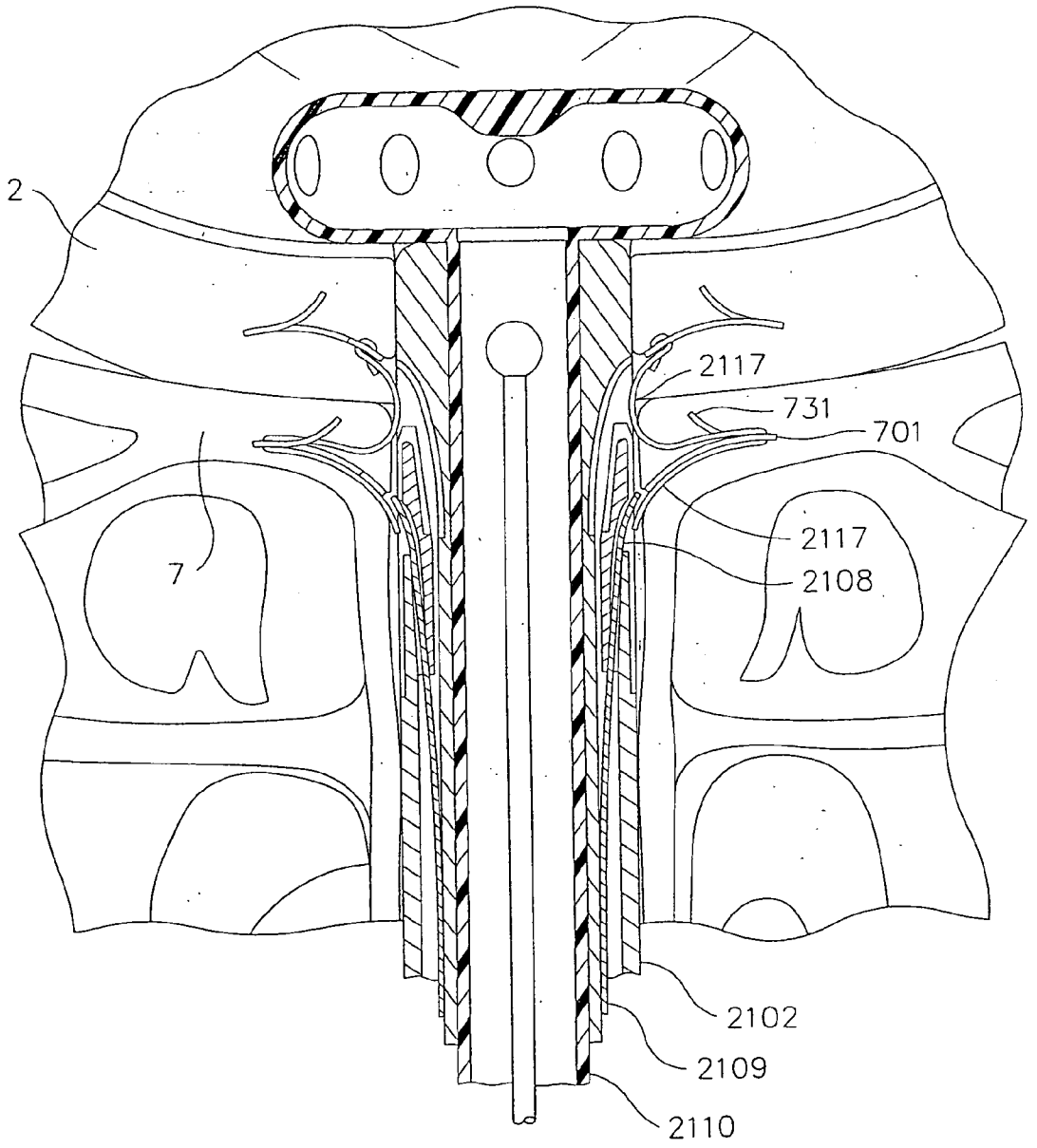

FIG. 107

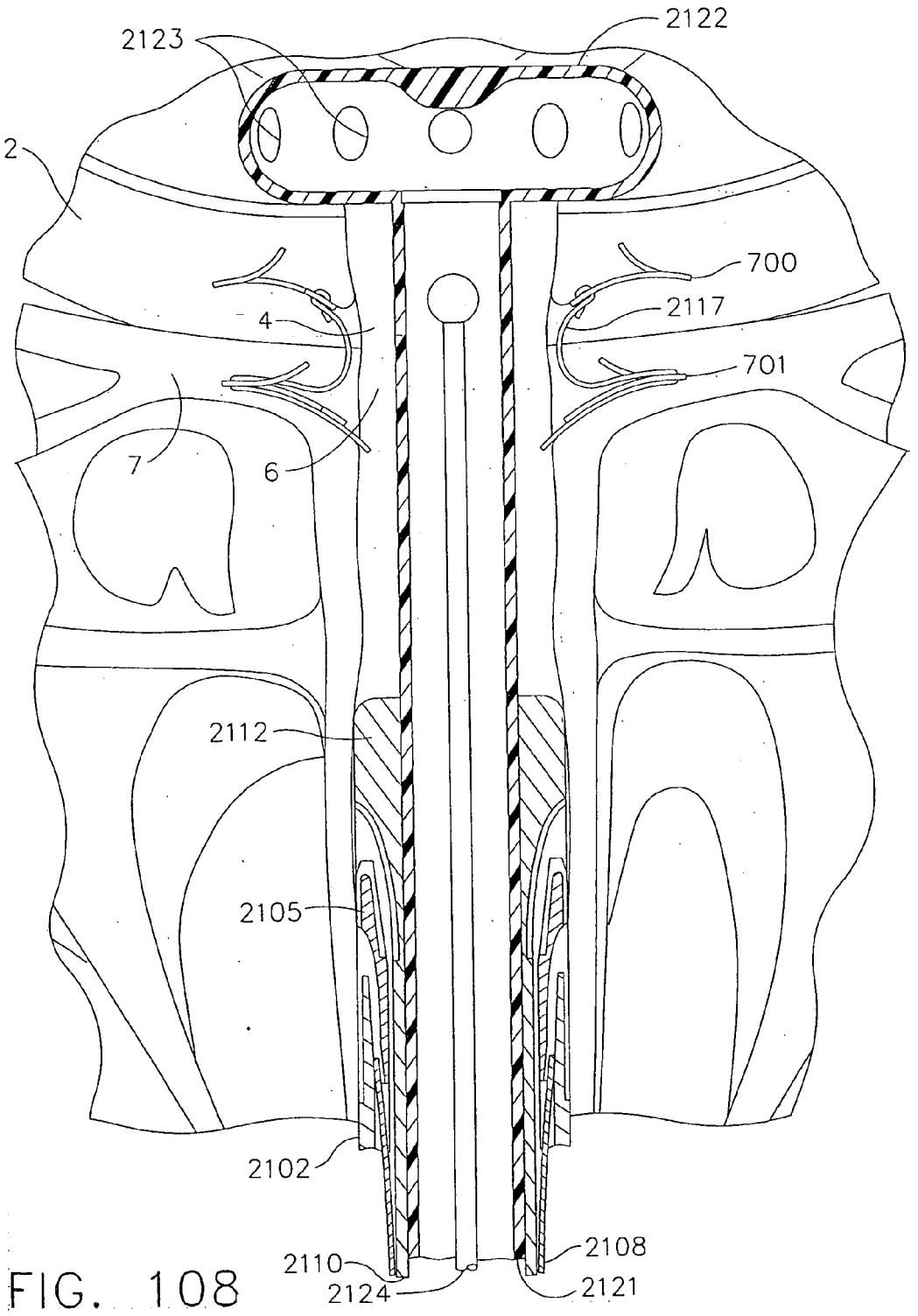
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FIG. 108

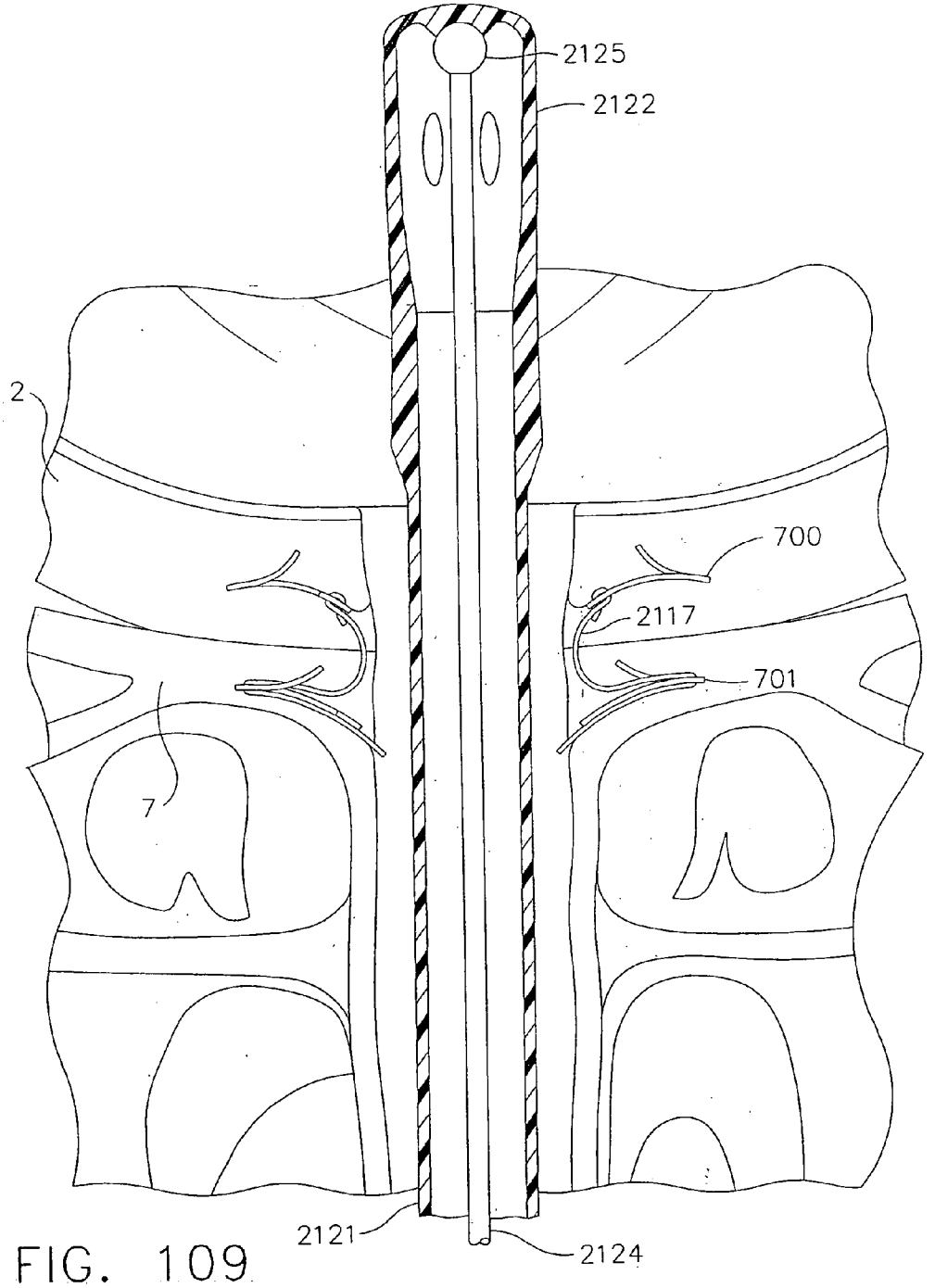

FIG. 109

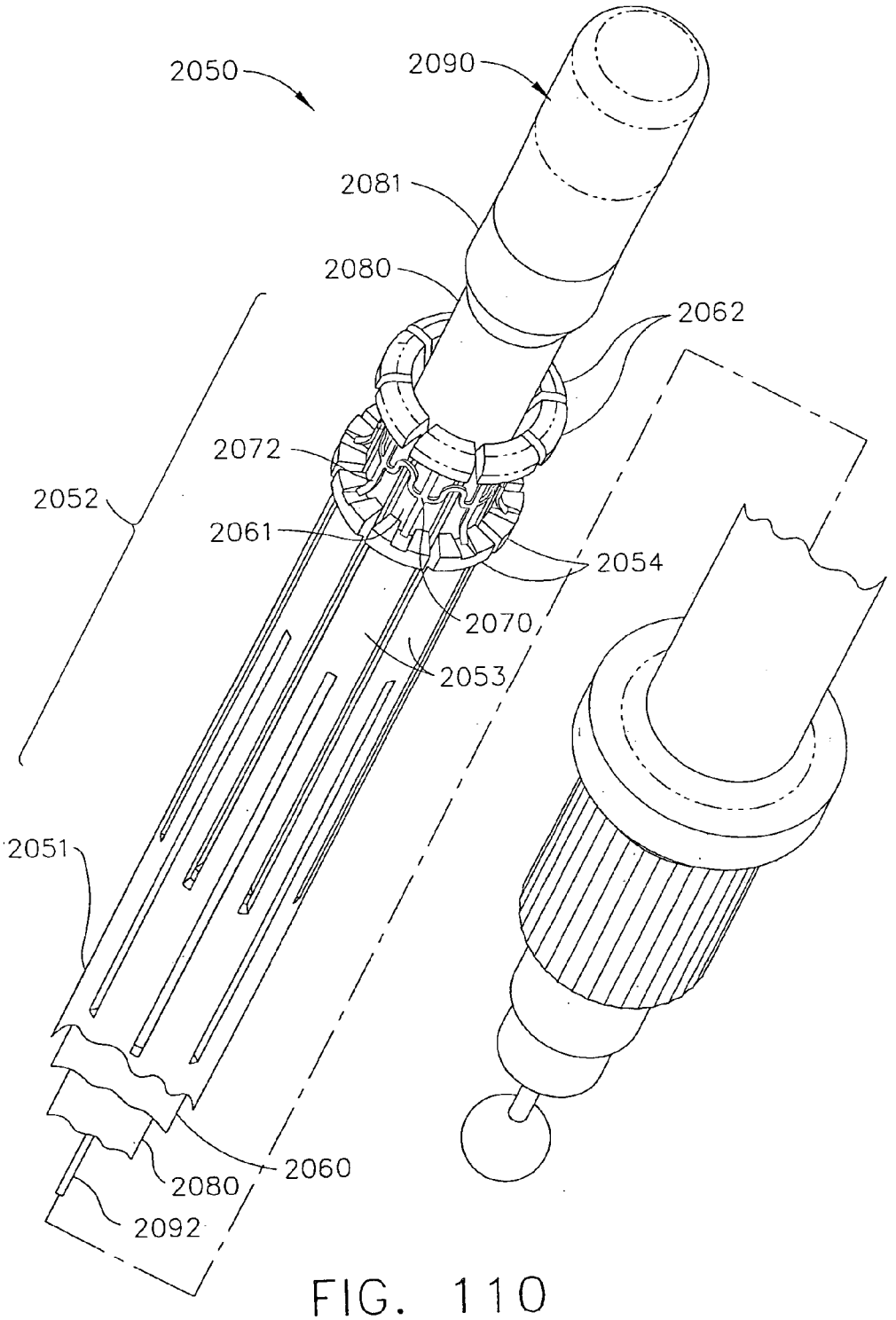
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FIG. 110

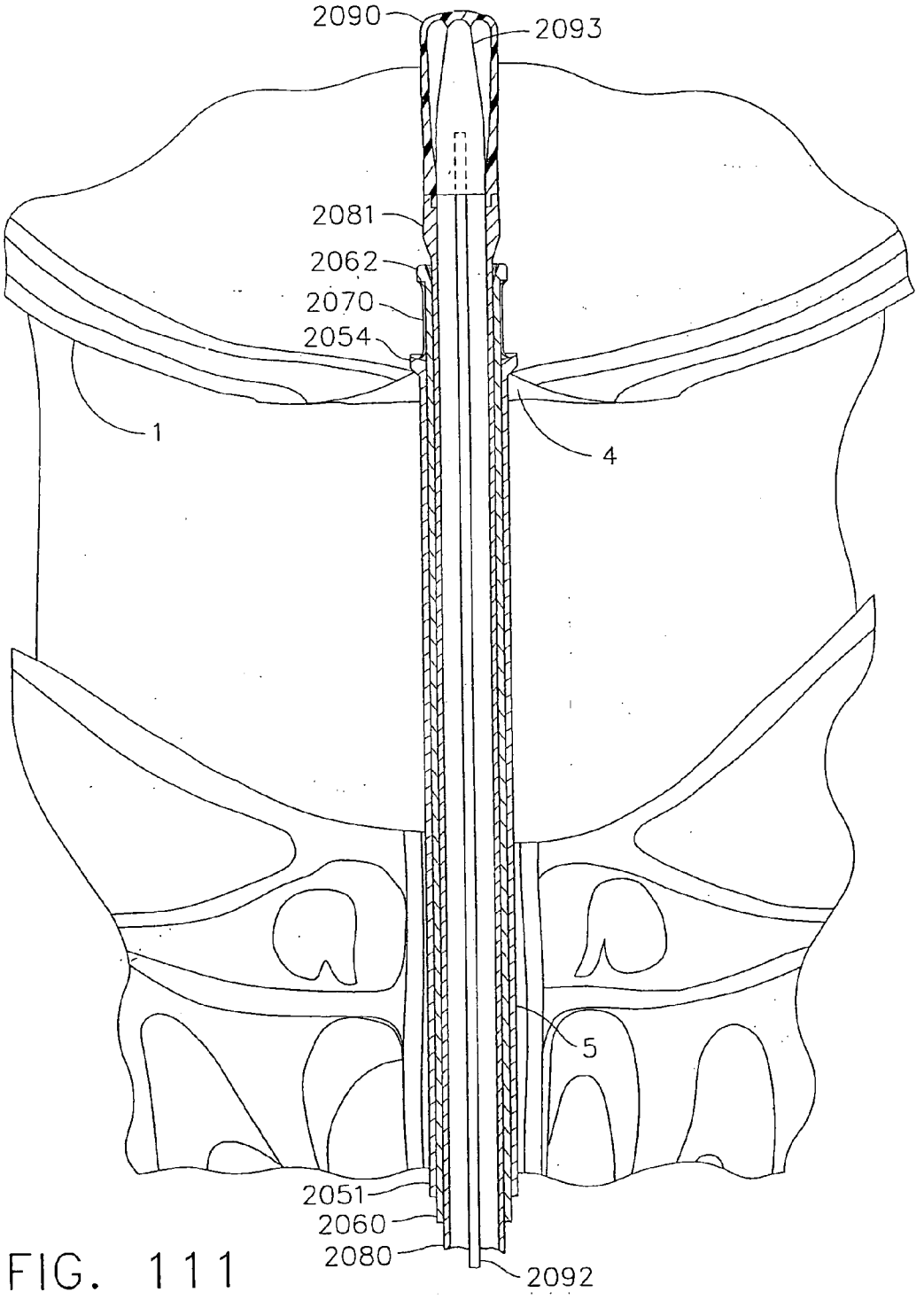

FIG. 111

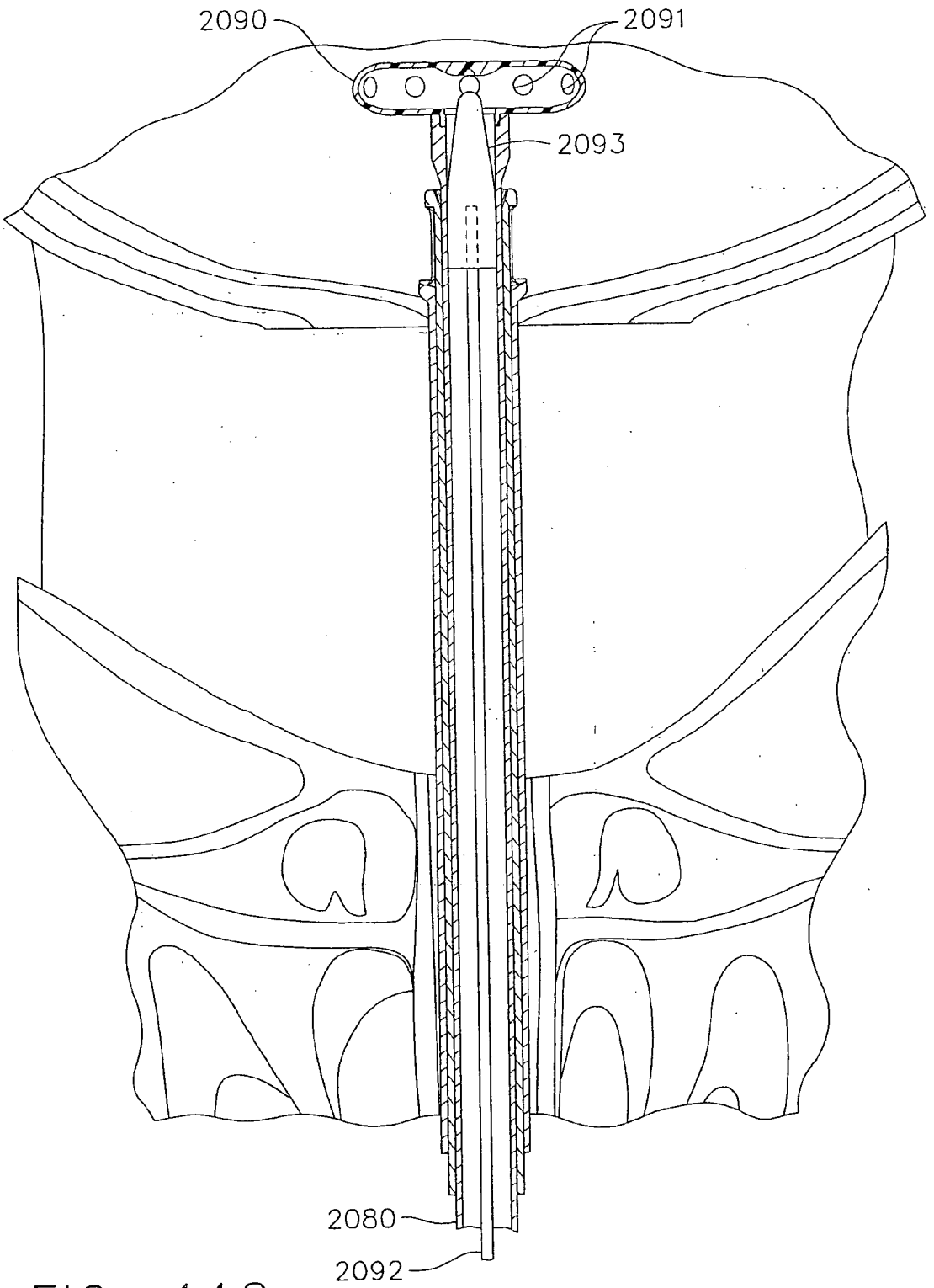

FIG. 112

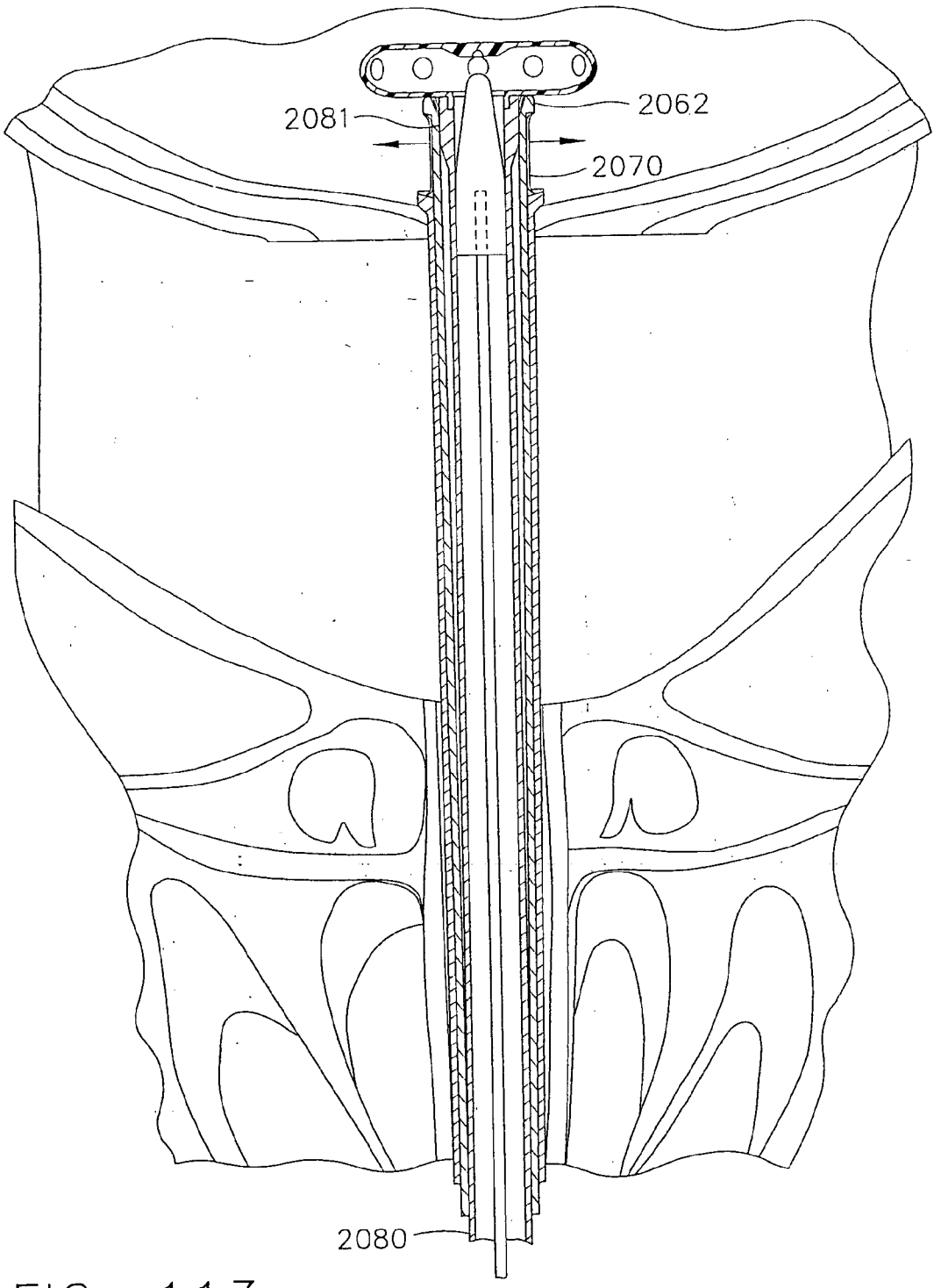

FIG. 113

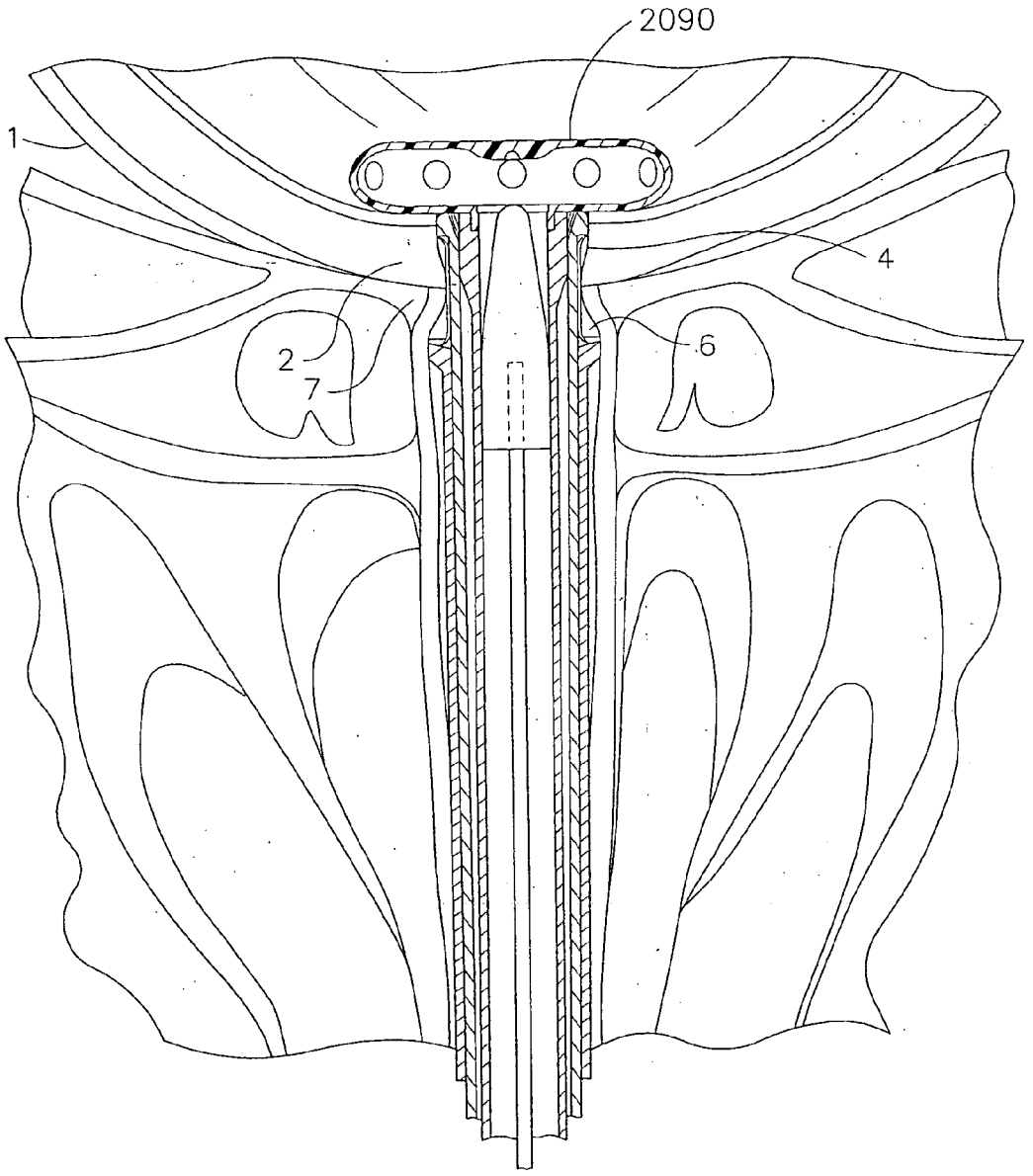

FIG. 114

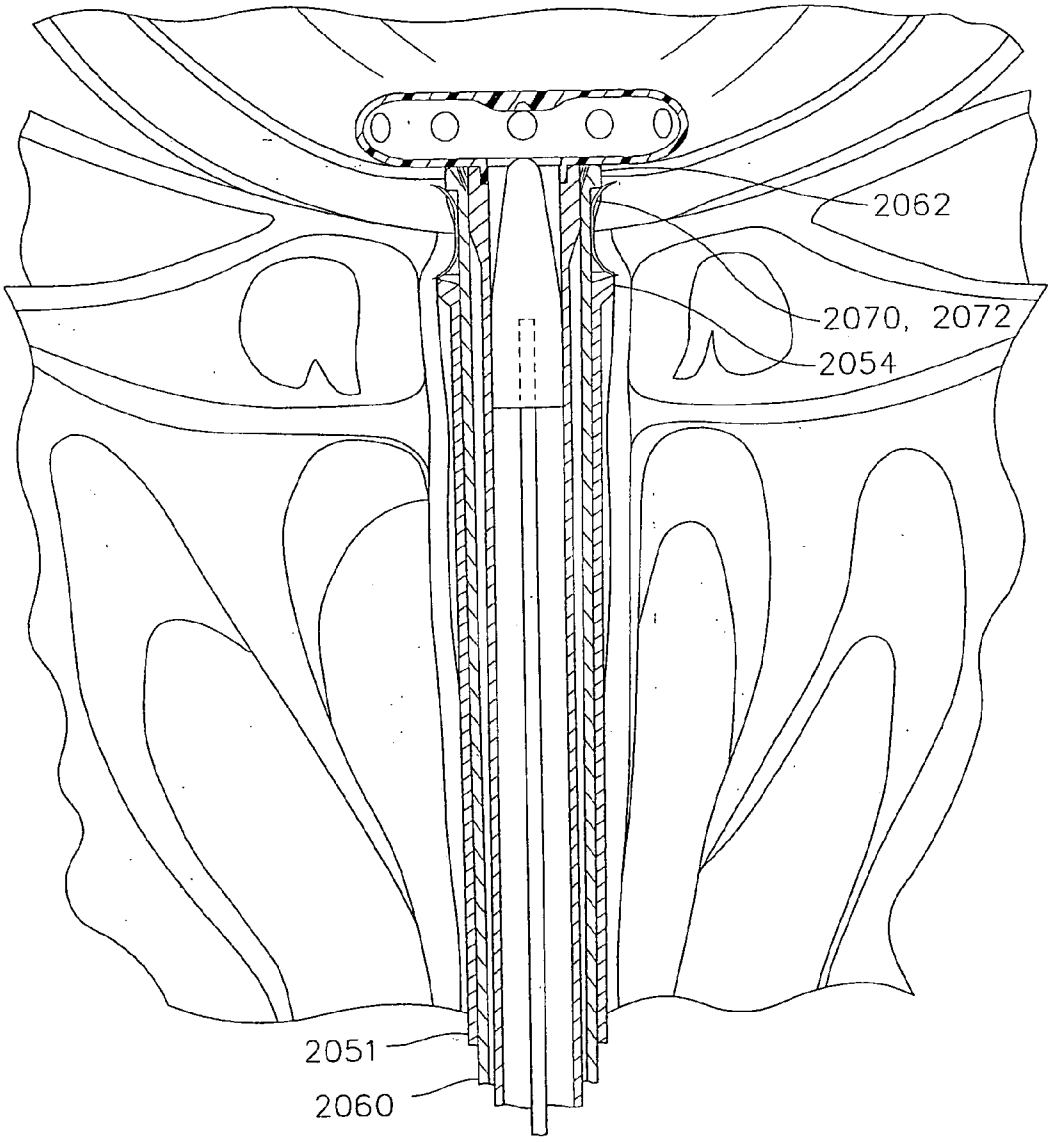

FIG. 115

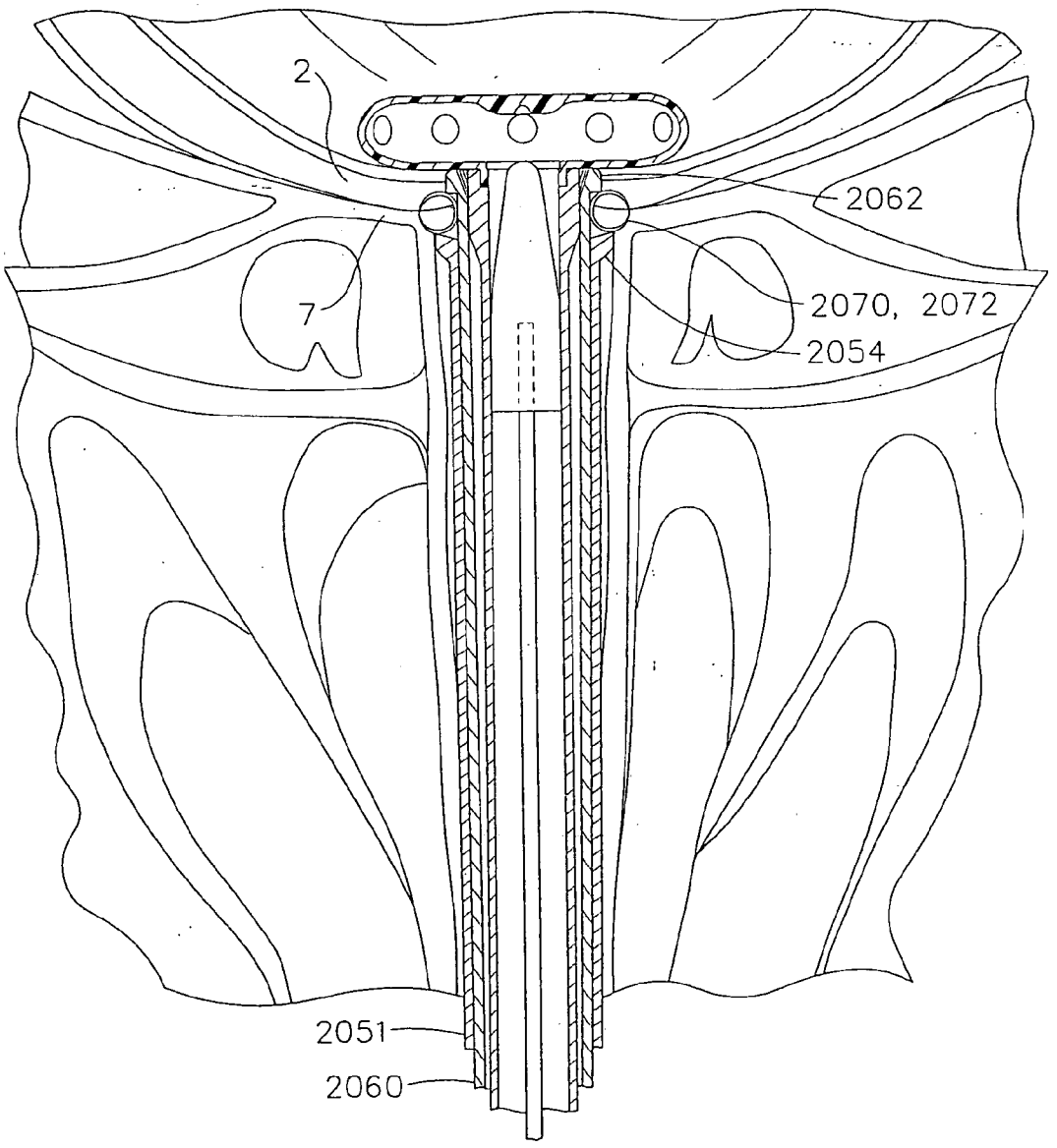

FIG. 116

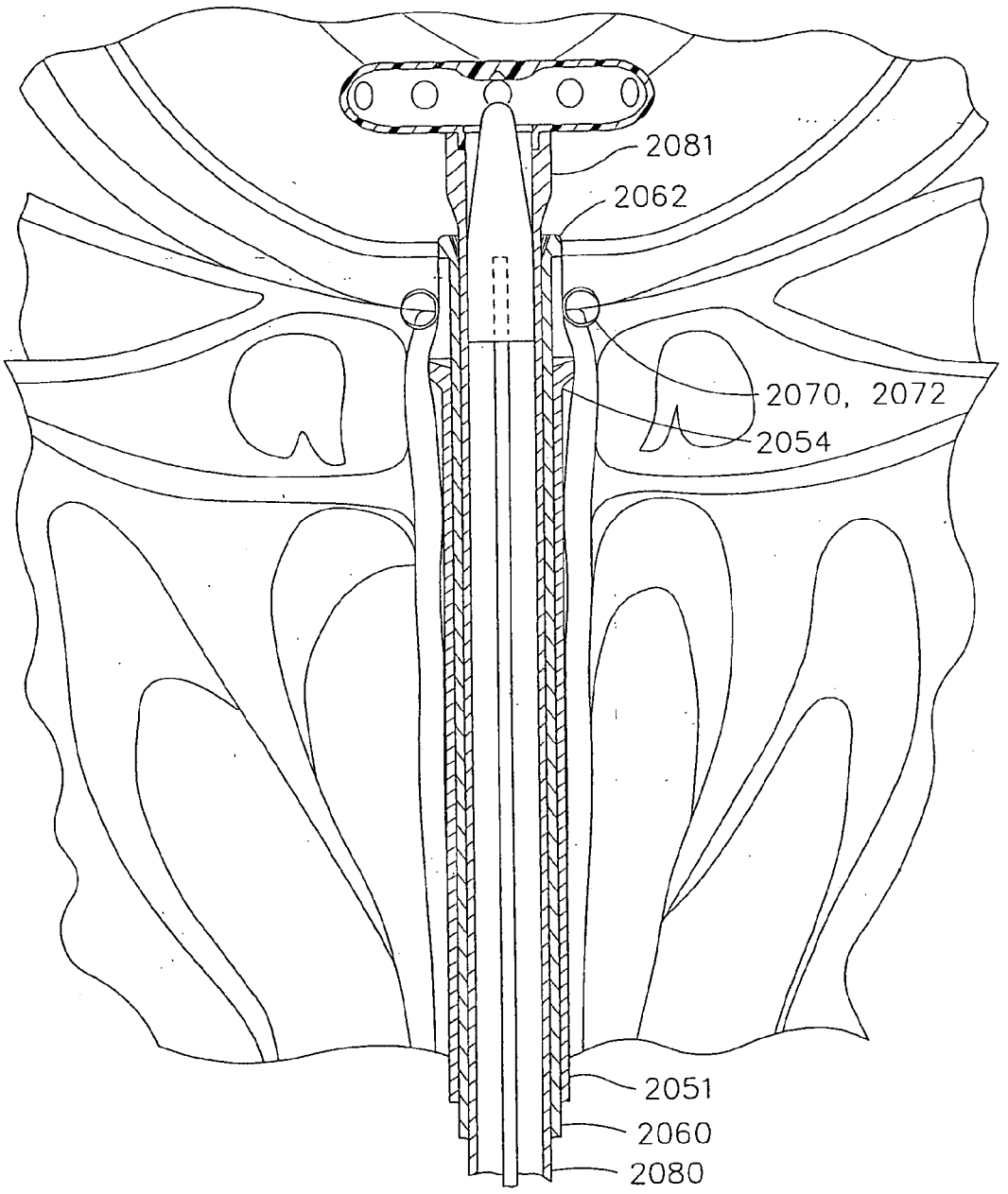

FIG. 117

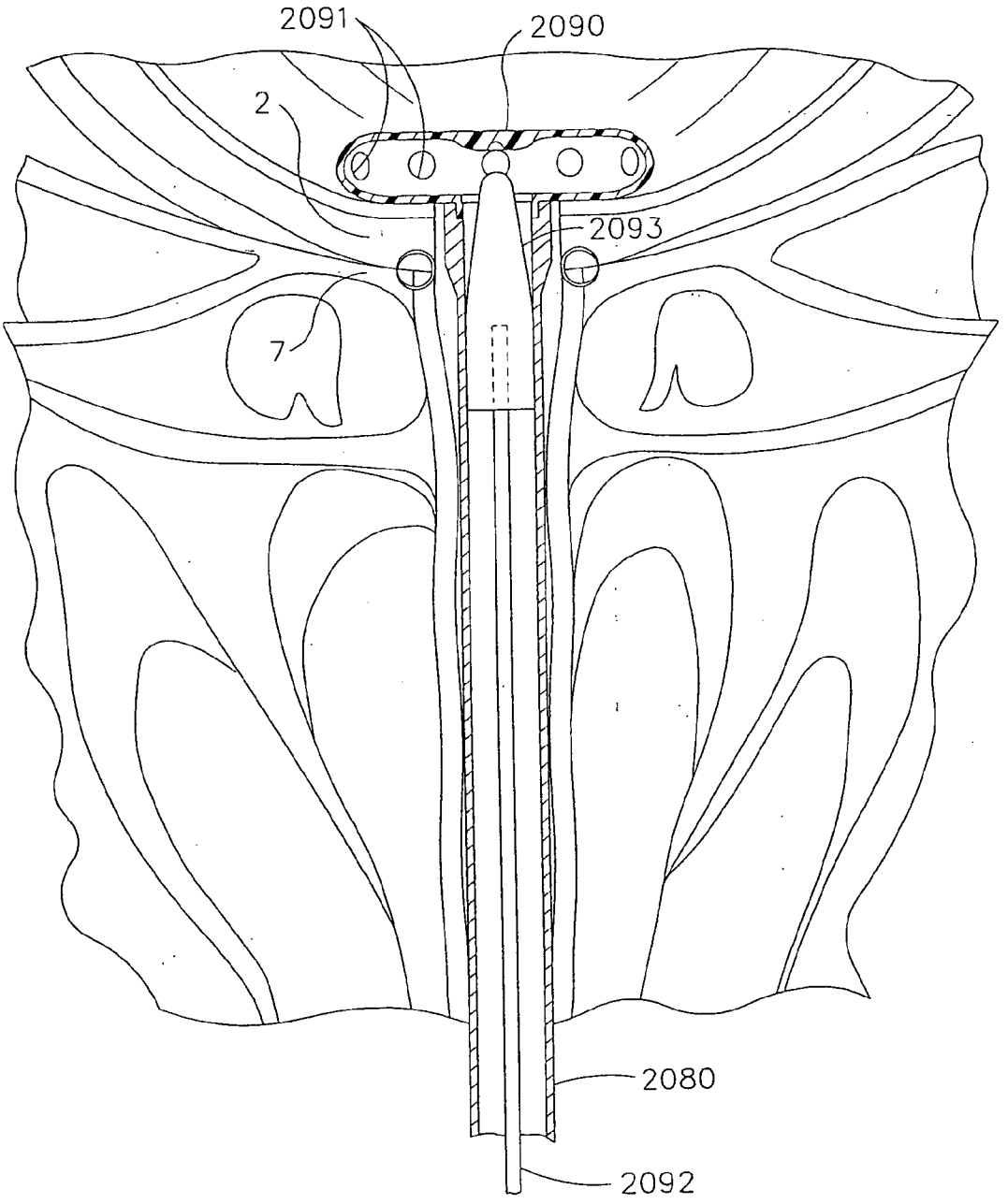

FIG. 118

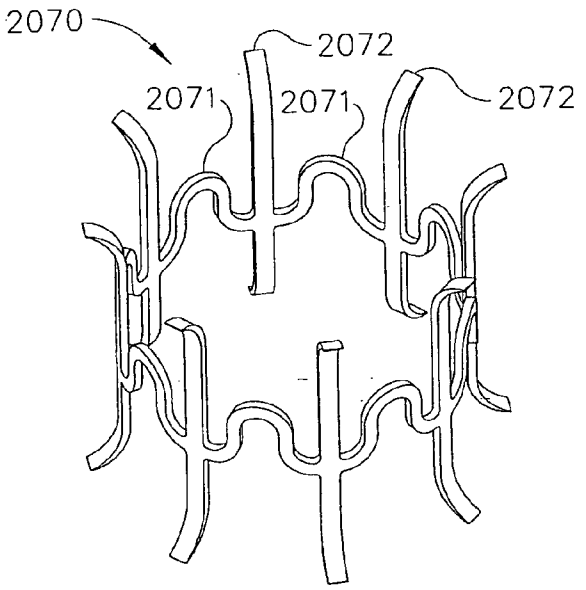

FIG. 119

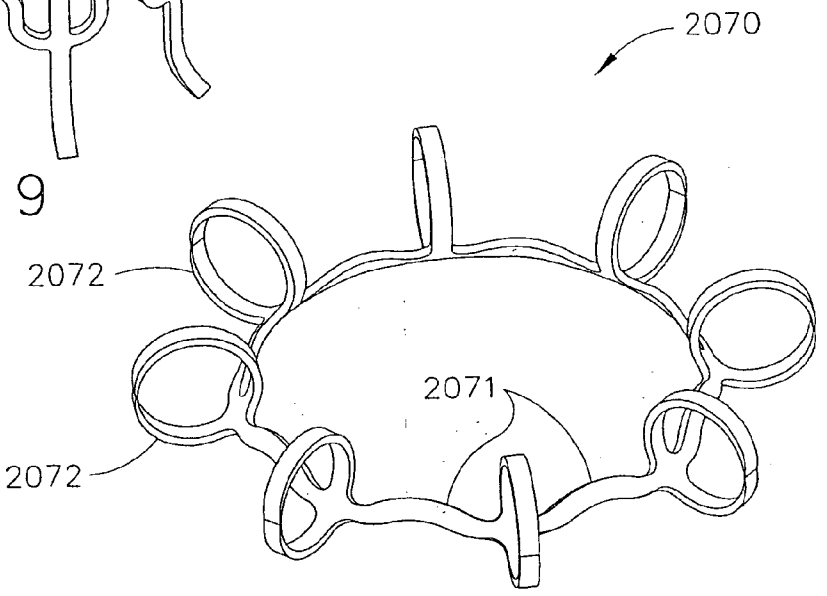

FIG. 120

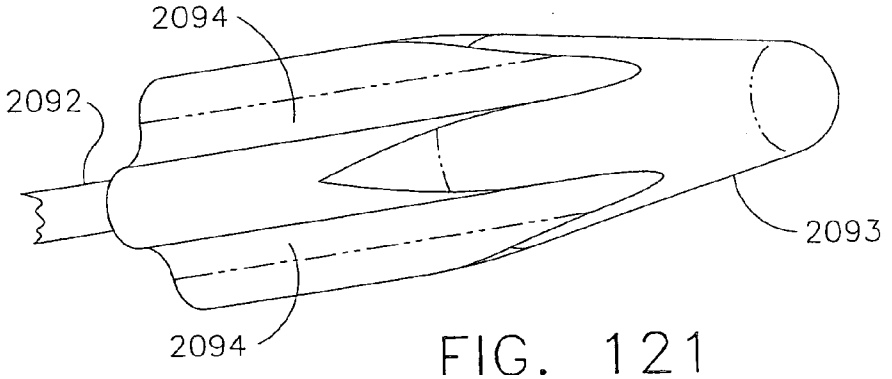

FIG. 121

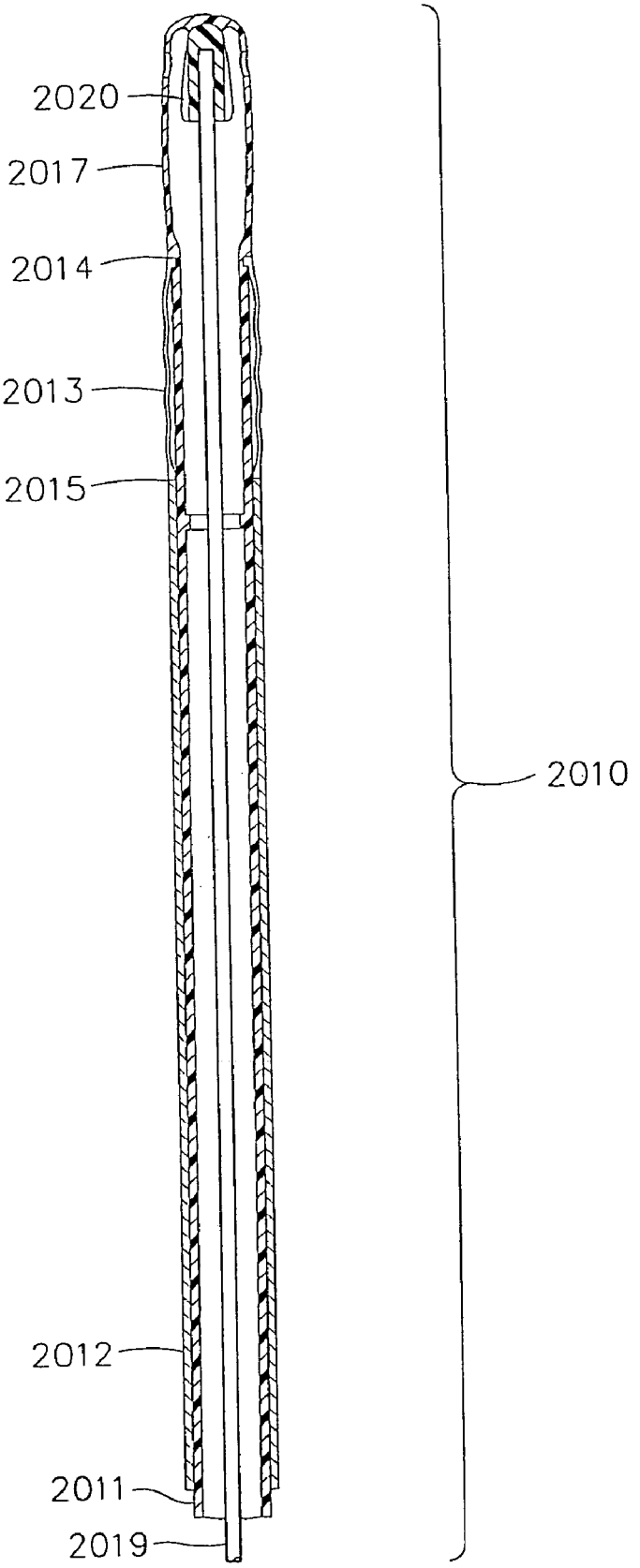

FIG. 122

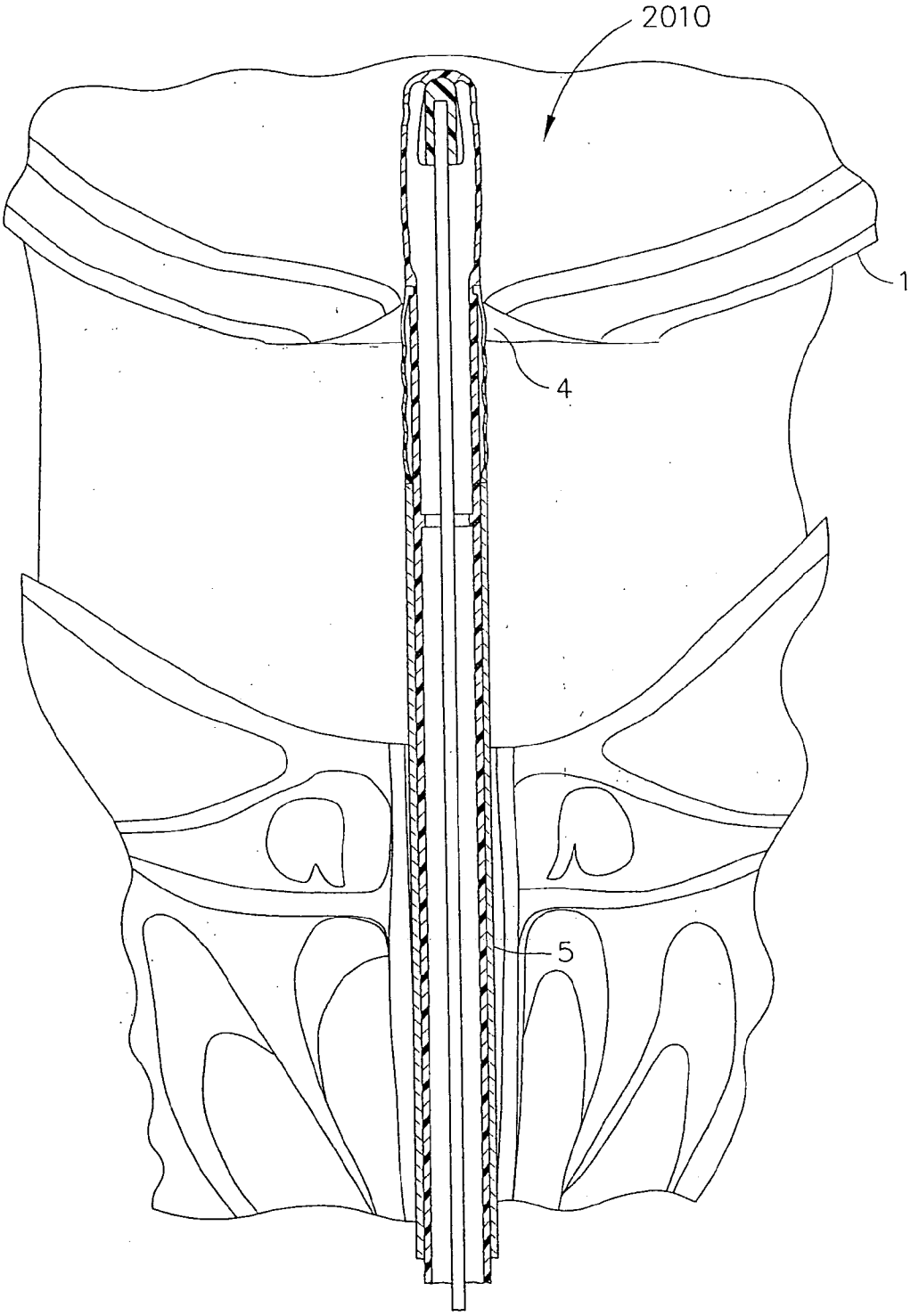

FIG. 123

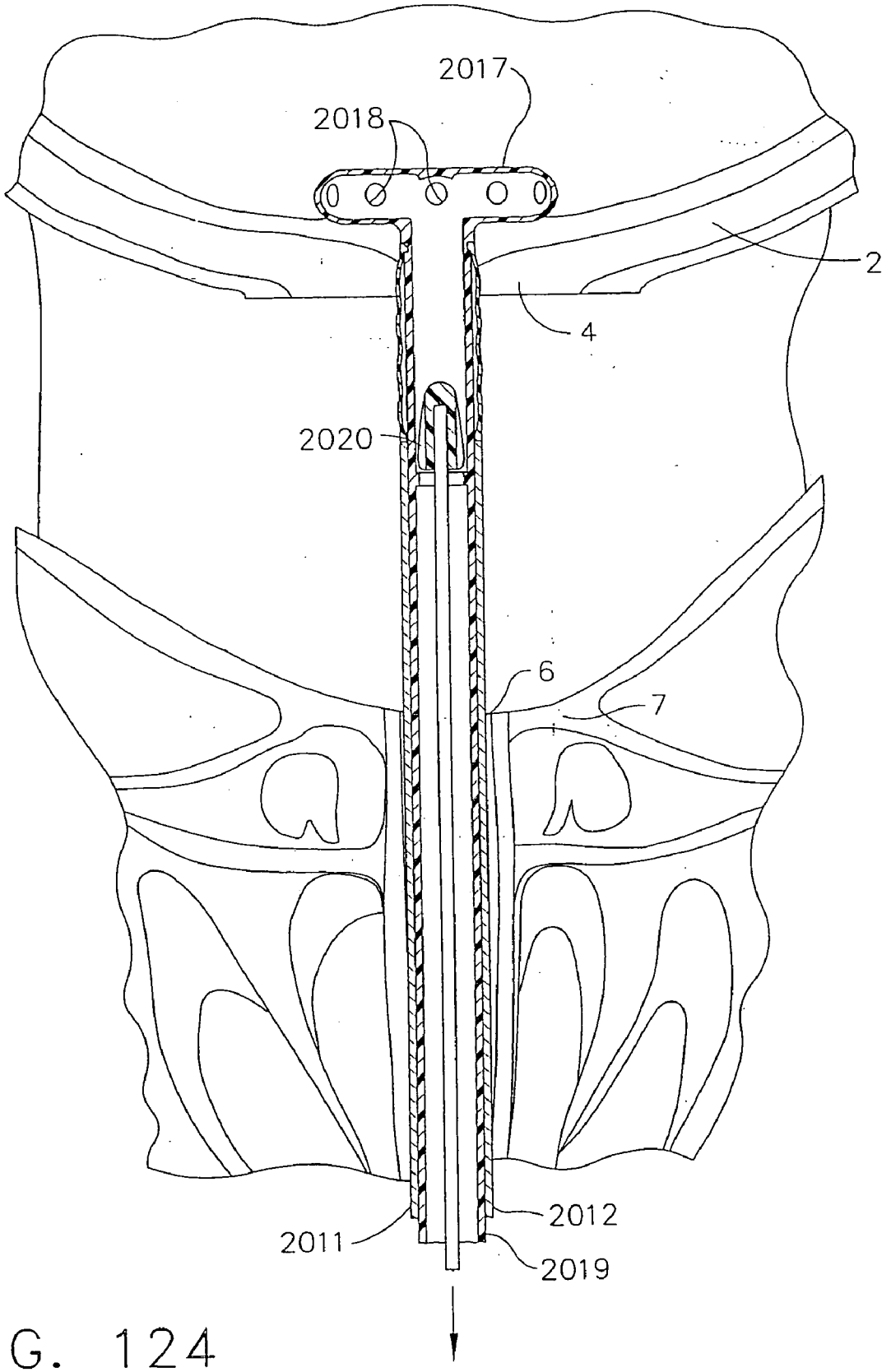

FIG. 124

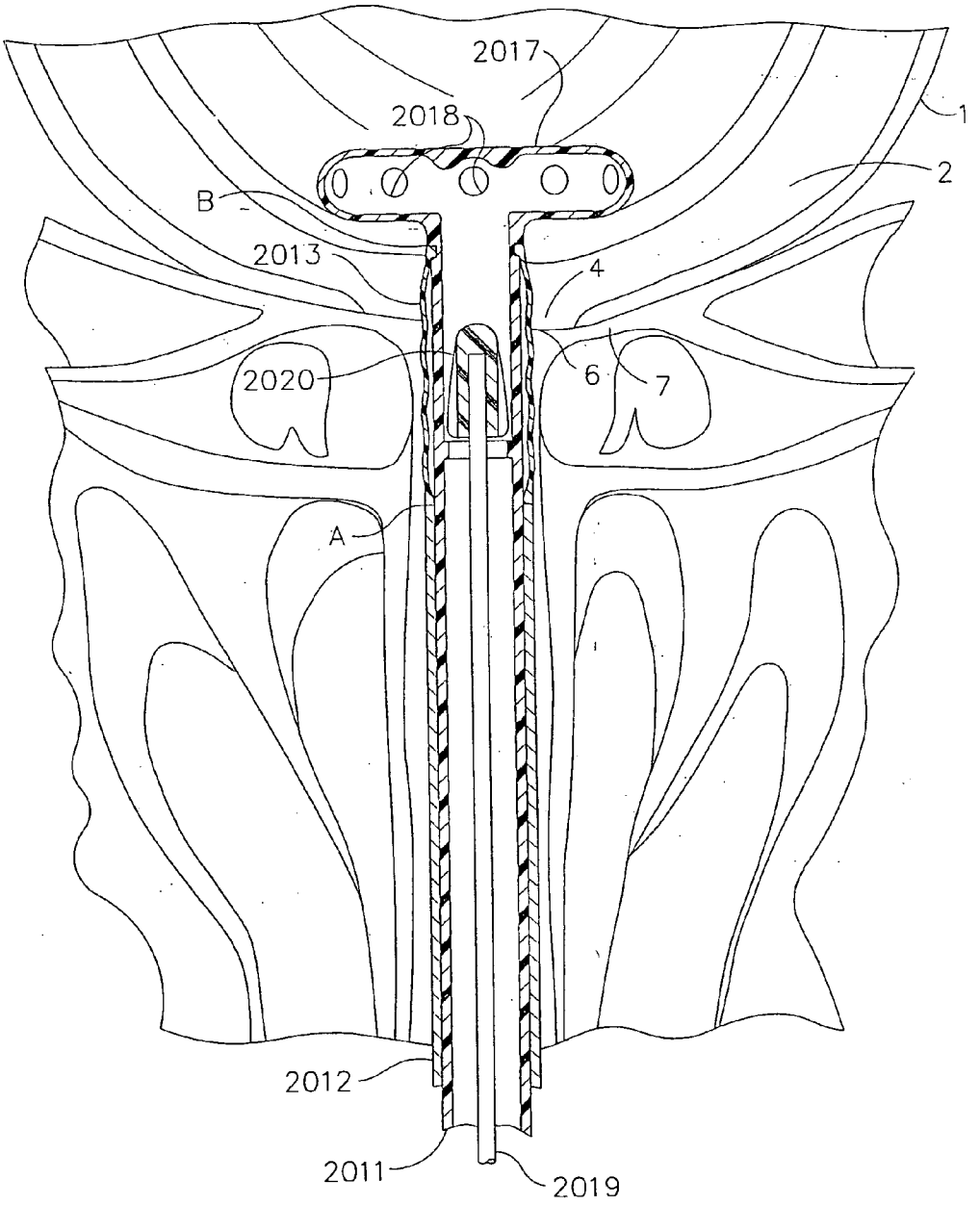

FIG. 125

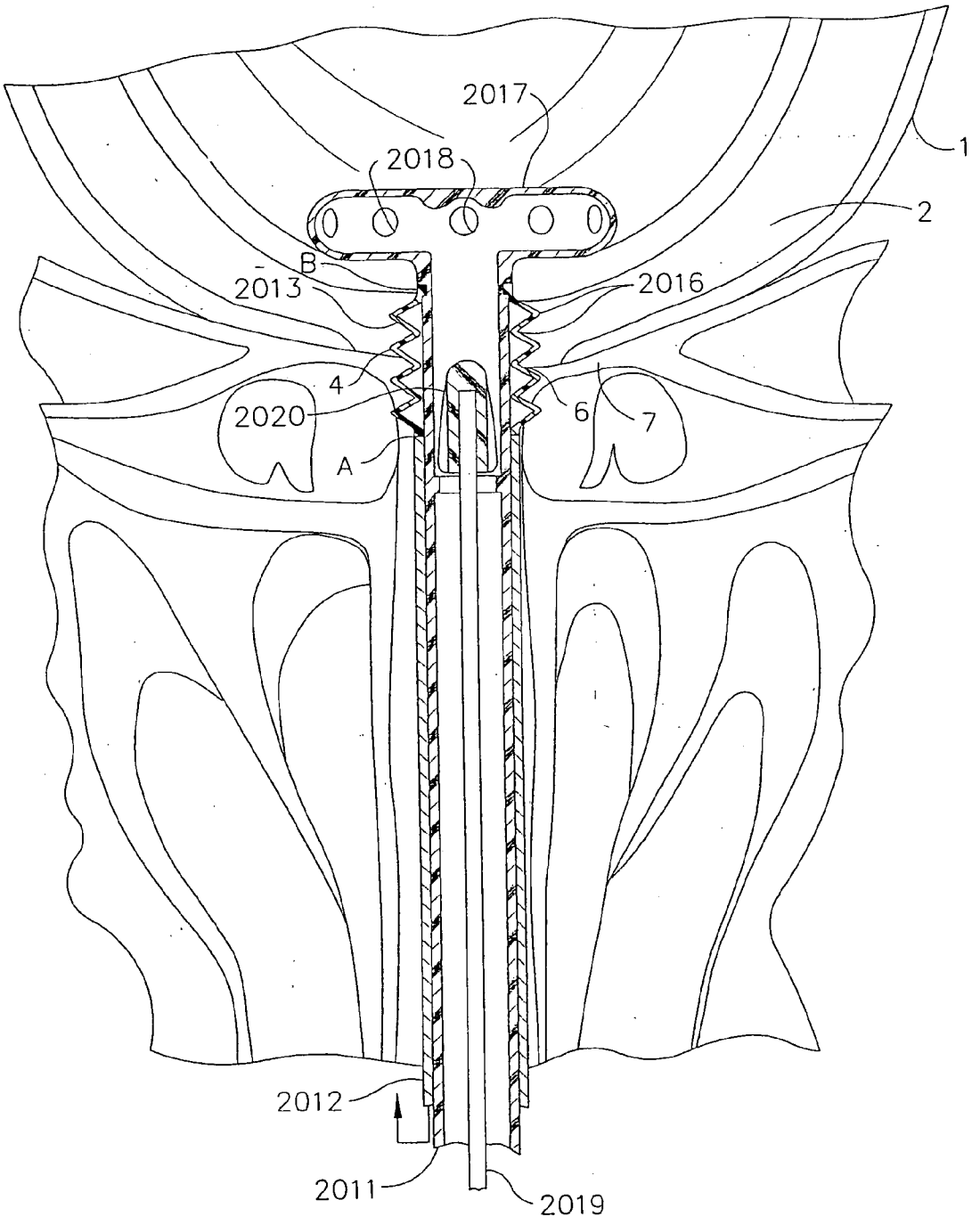

FIG. 126

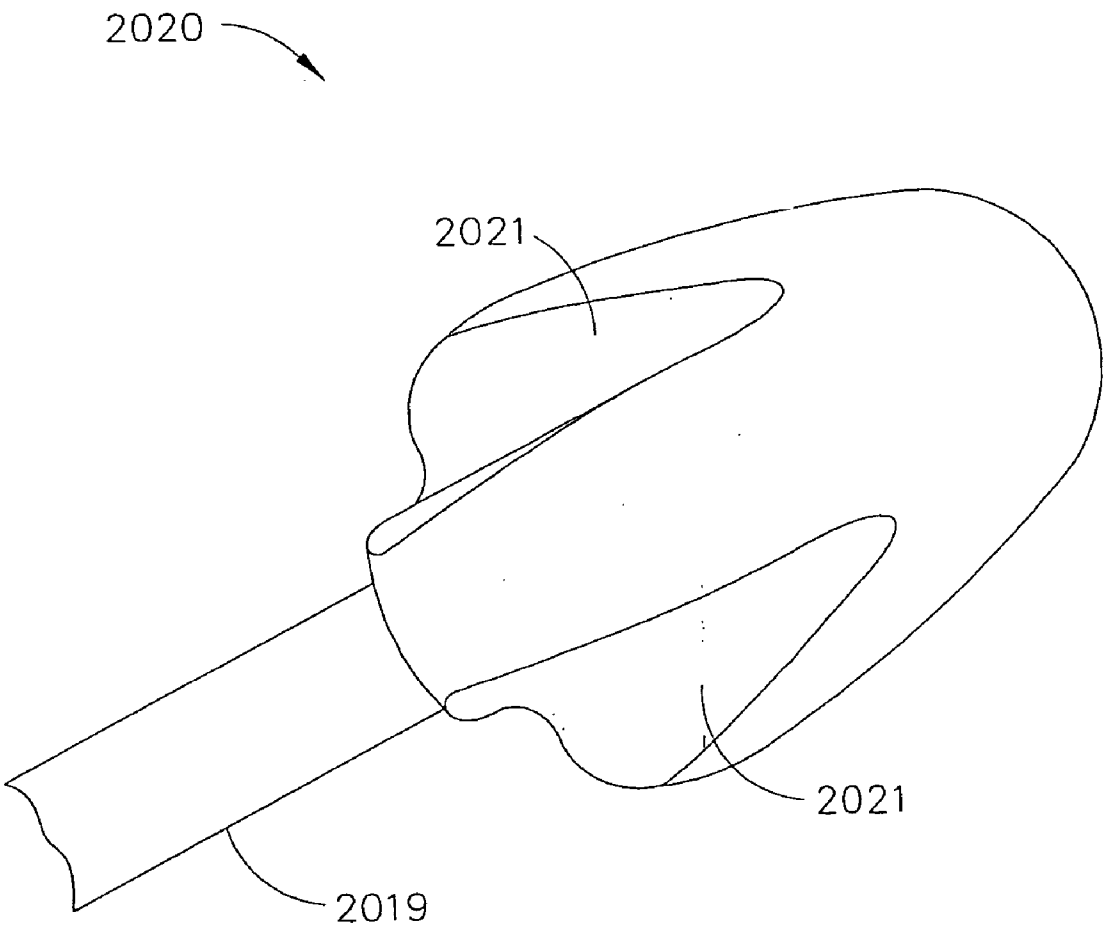

FIG. 127

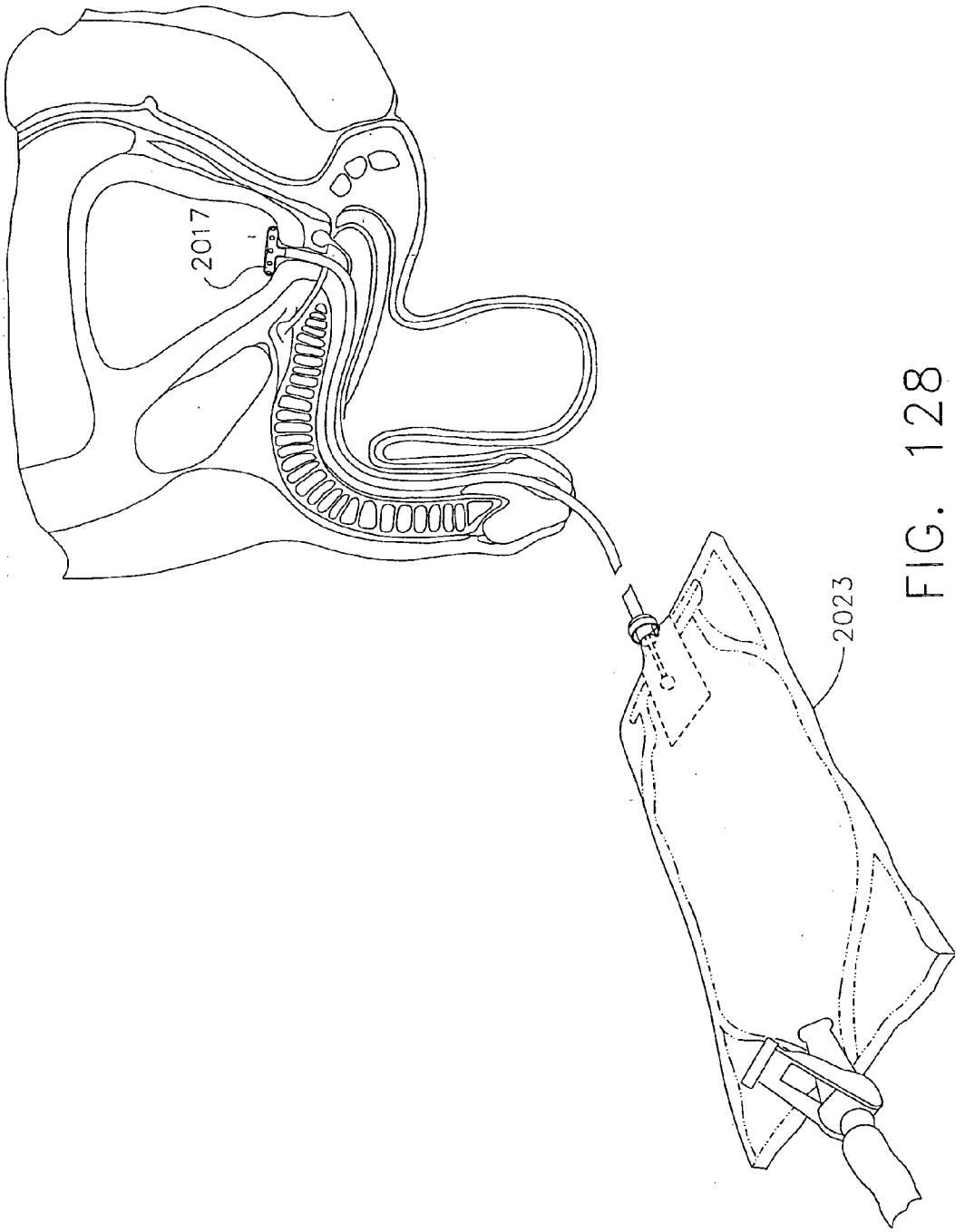

FIG. 128

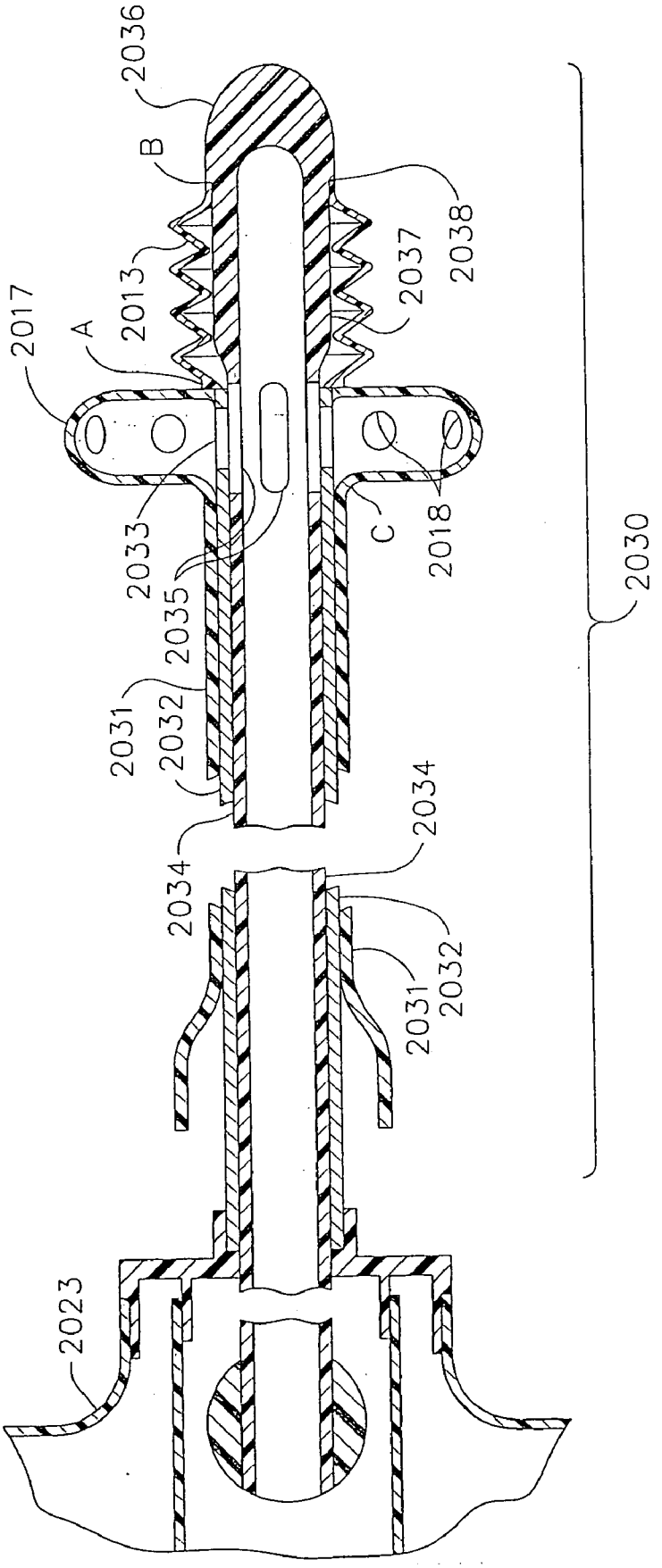
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FIG. 129

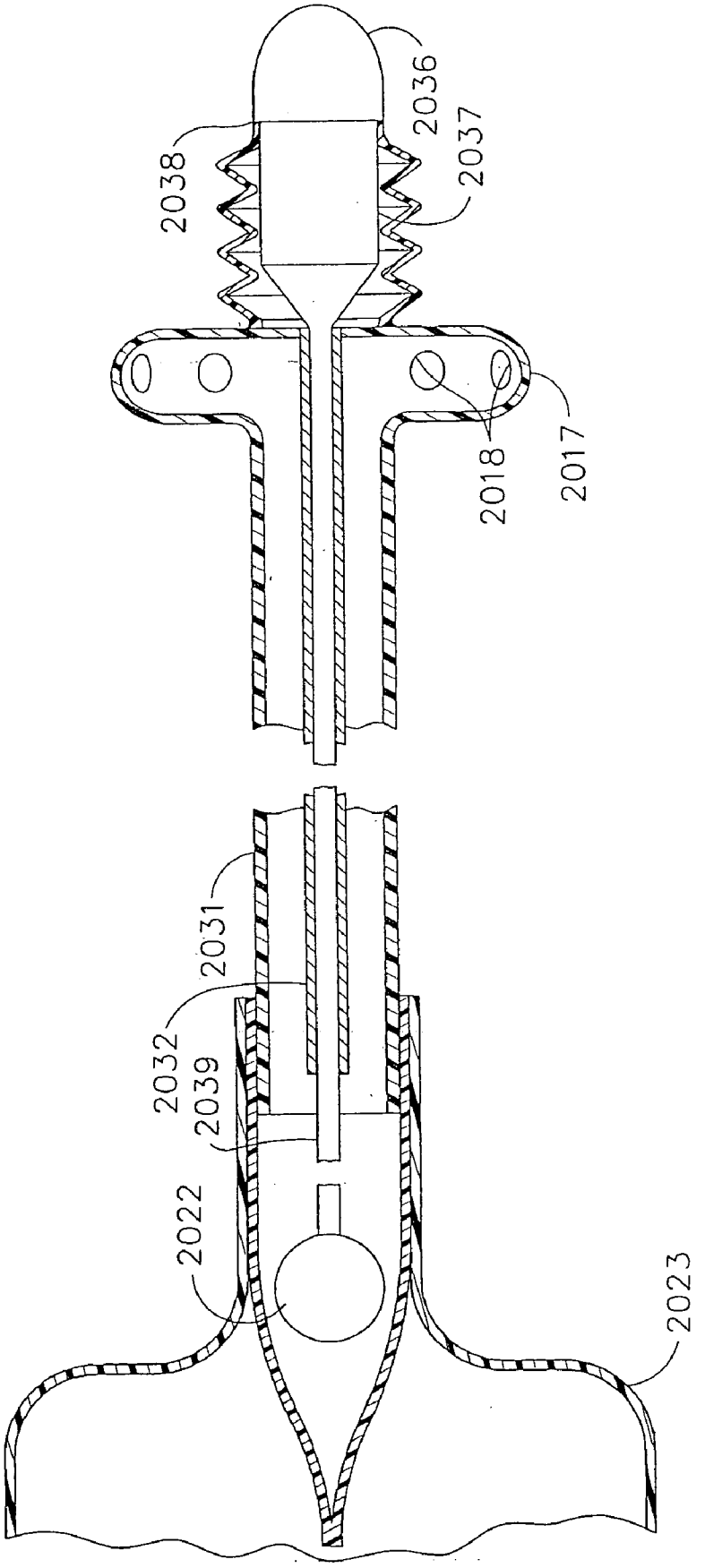

FIG. 130

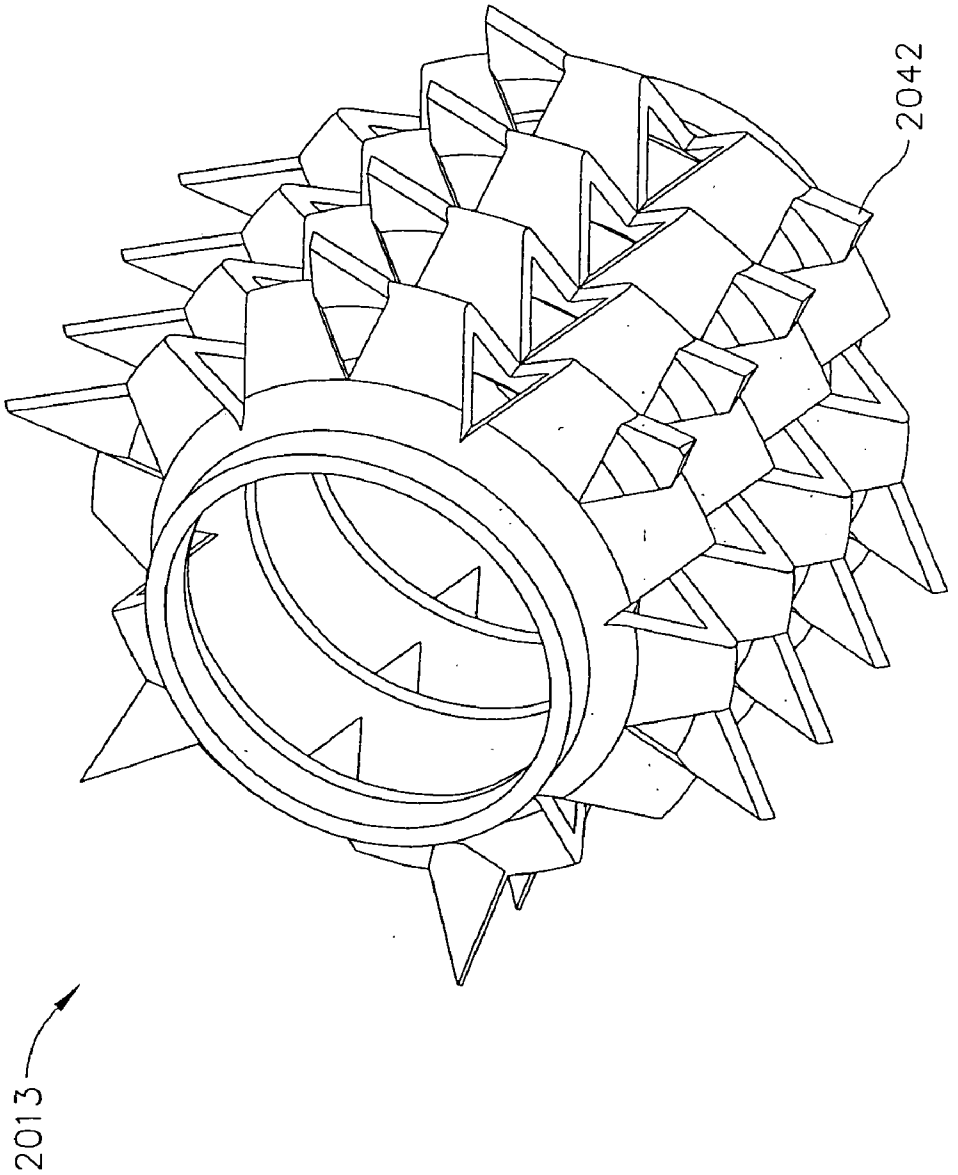

FIG. 131

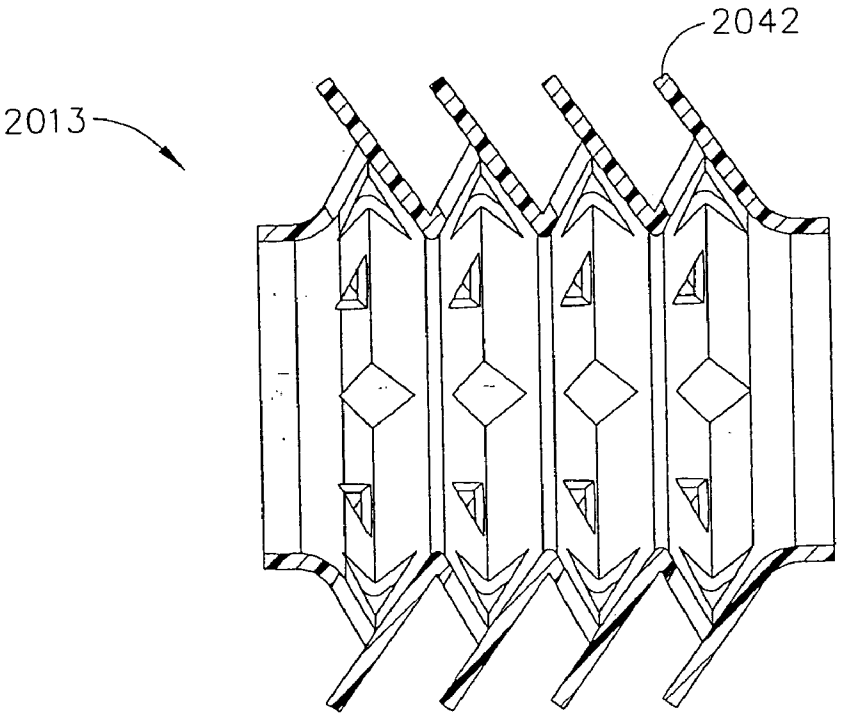

FIG. 132

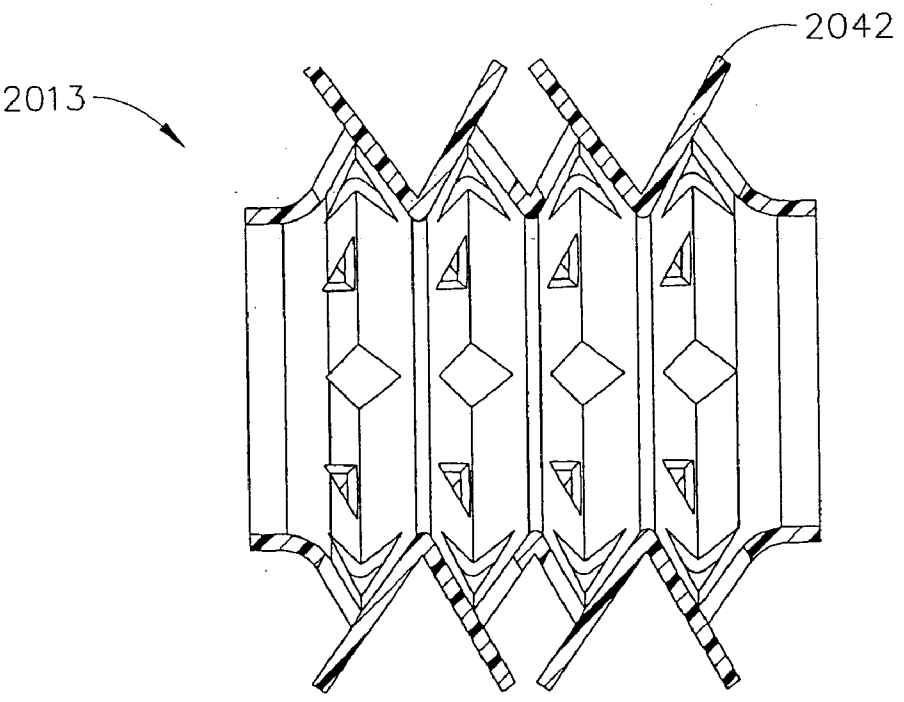

FIG. 133

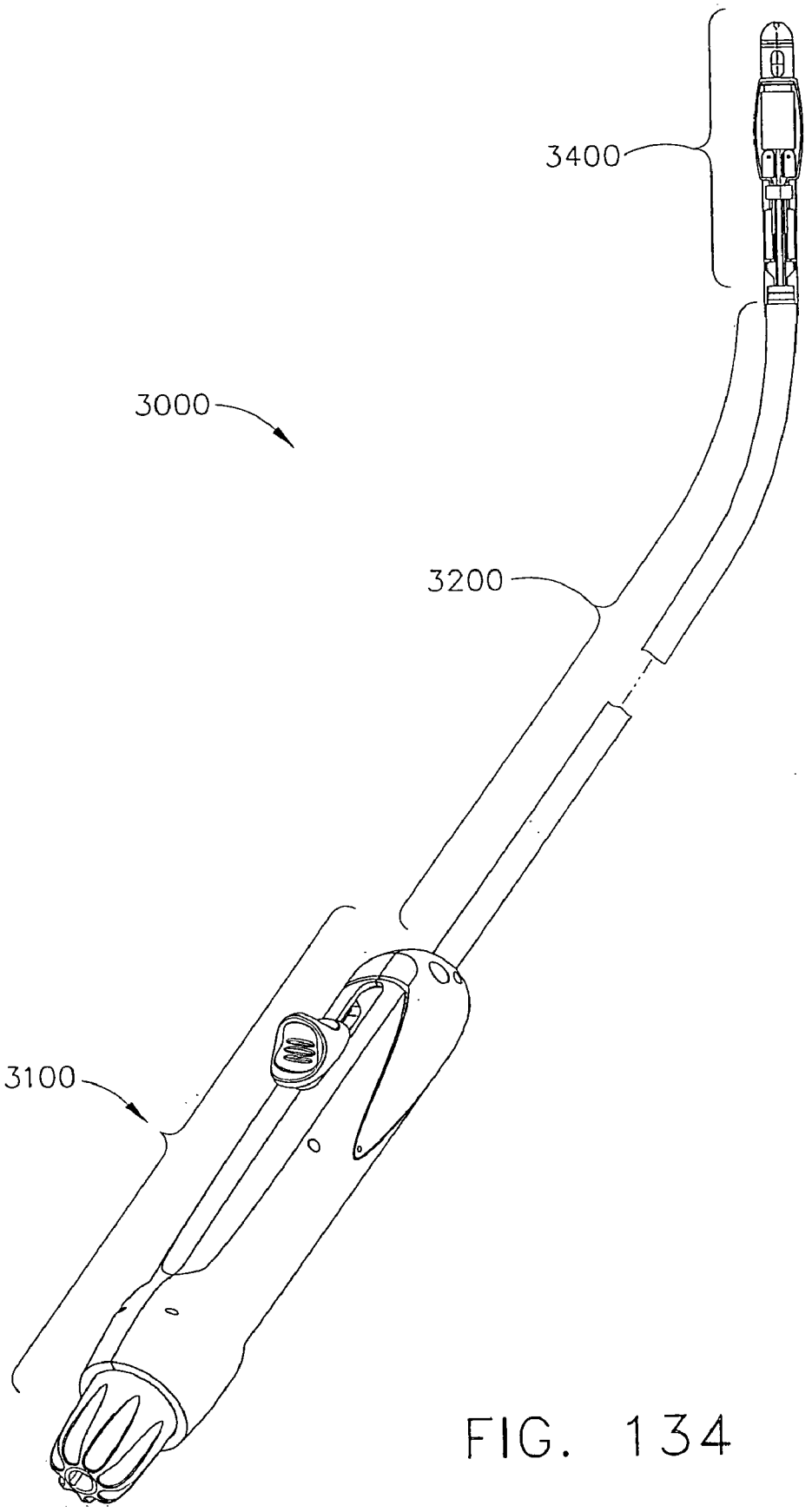

FIG. 134

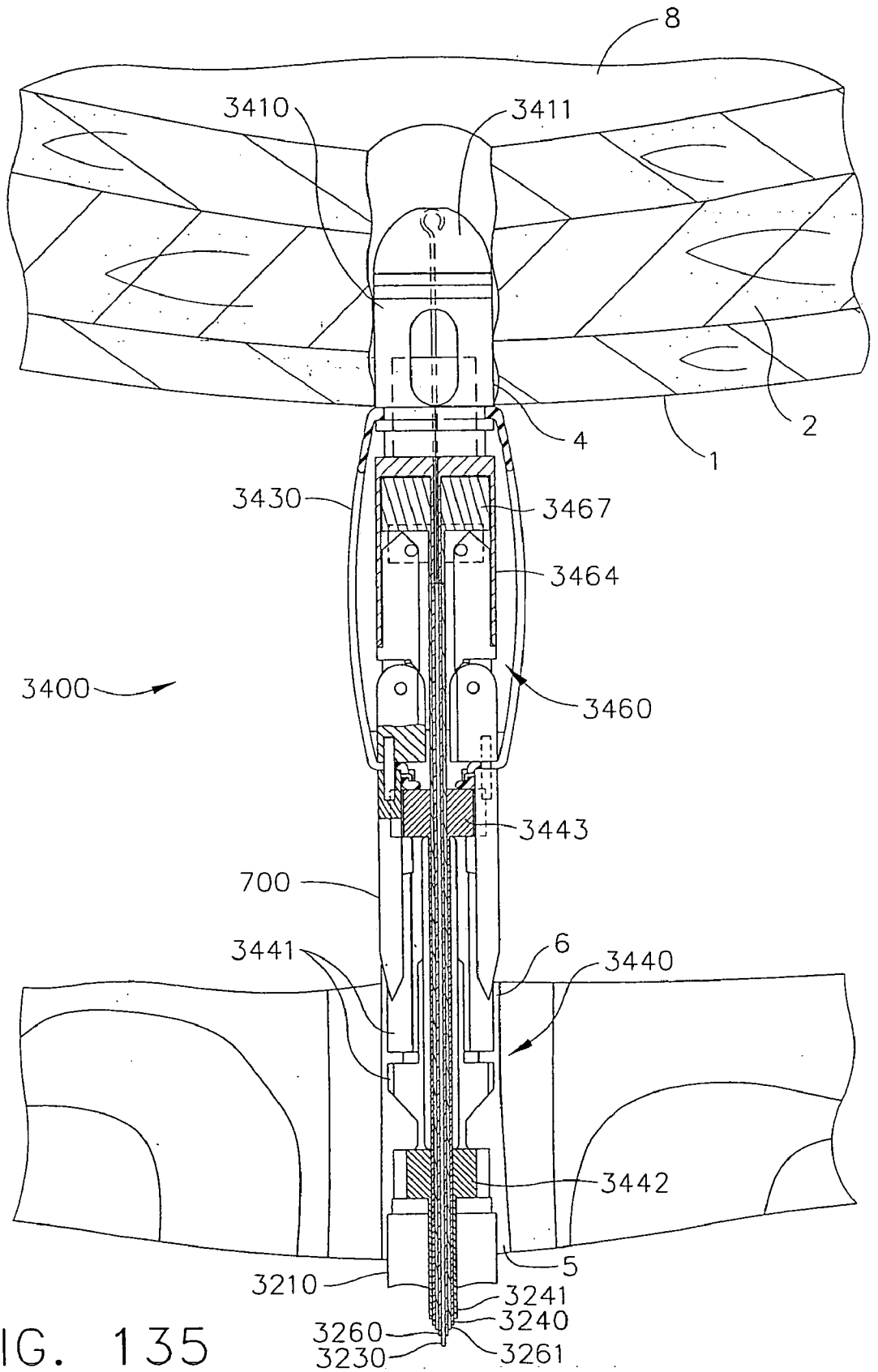
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FIG. 135

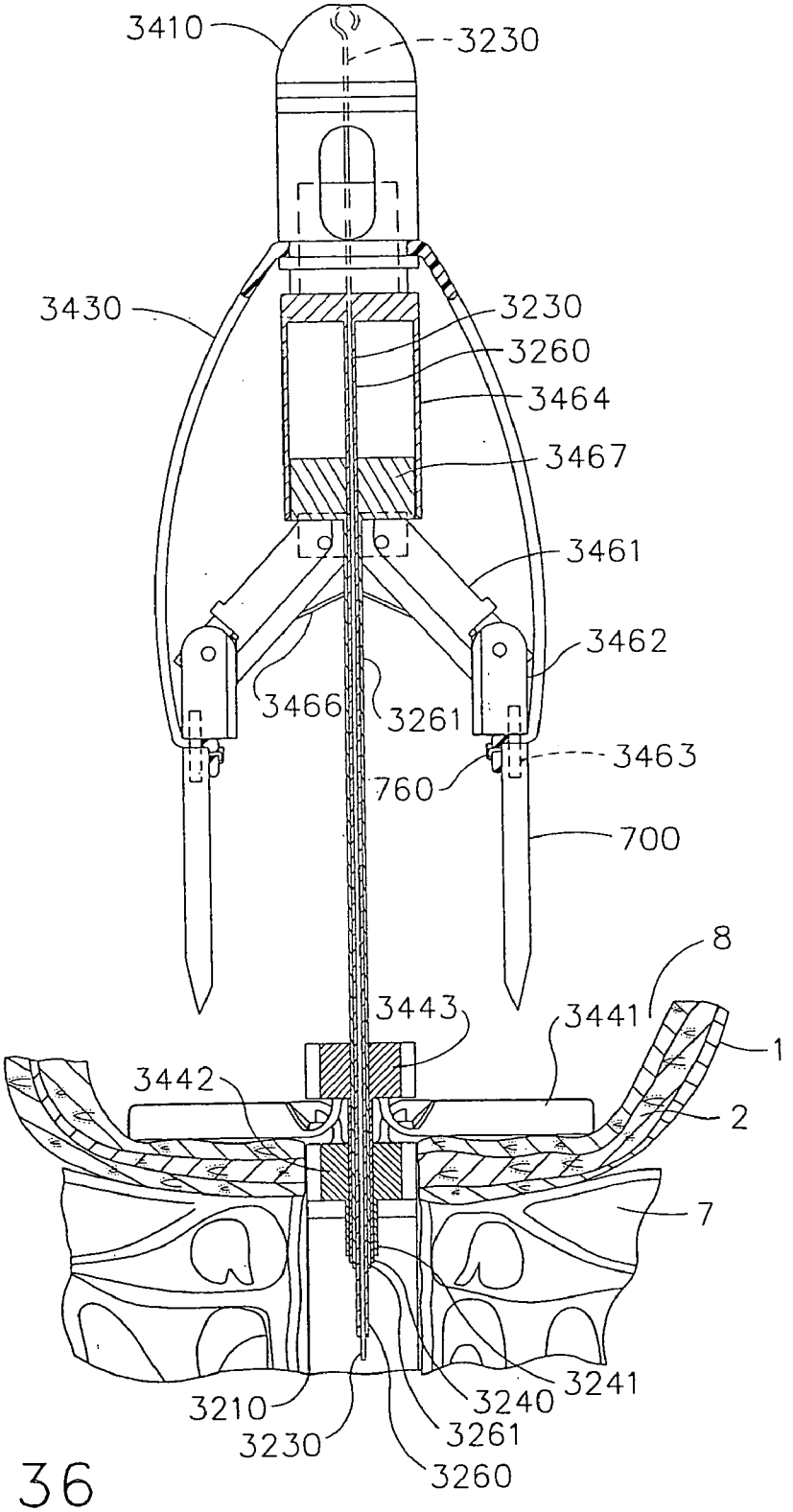
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FIG. 136

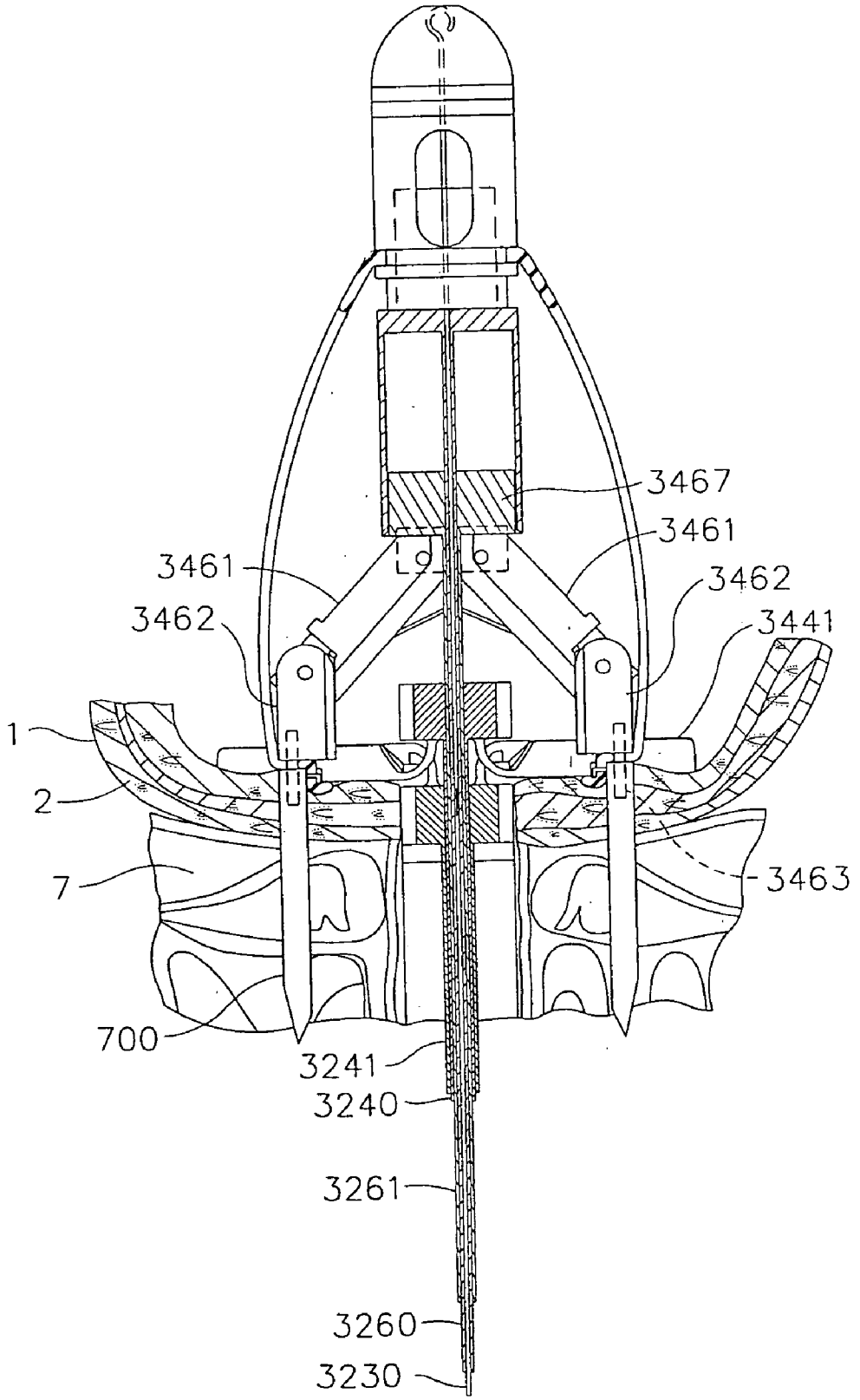
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FIG. 137

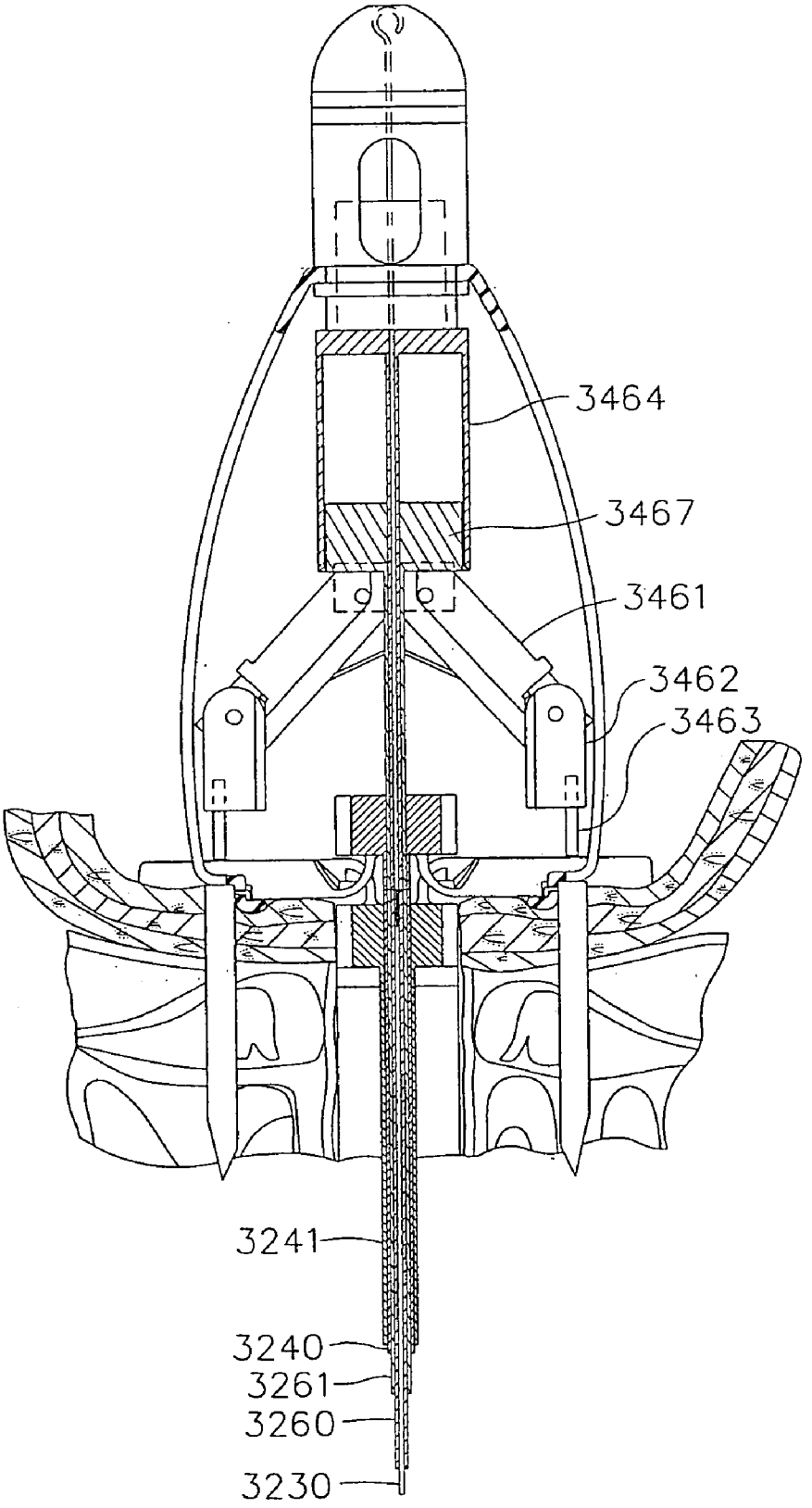

FIG. 138

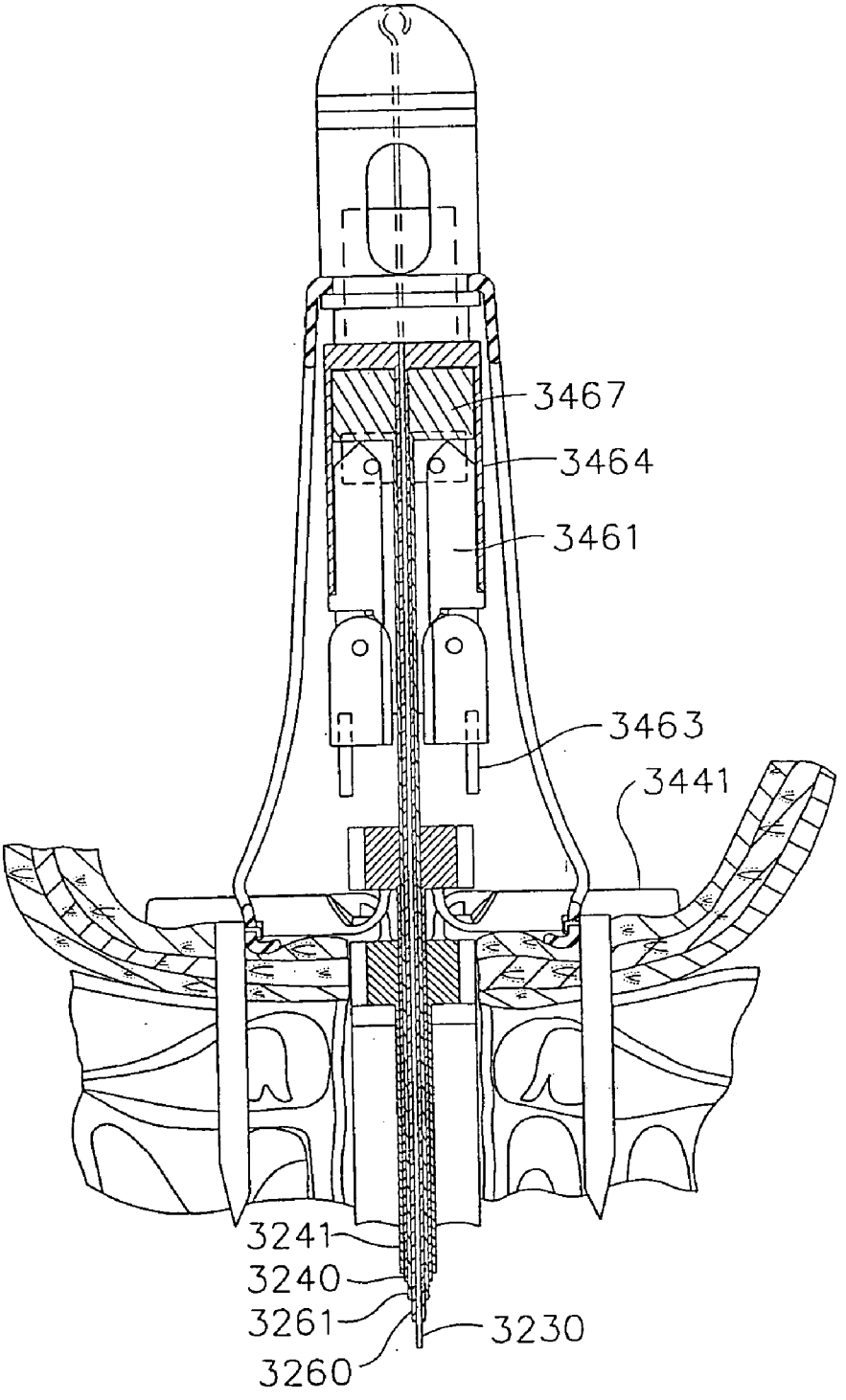

FIG. 139

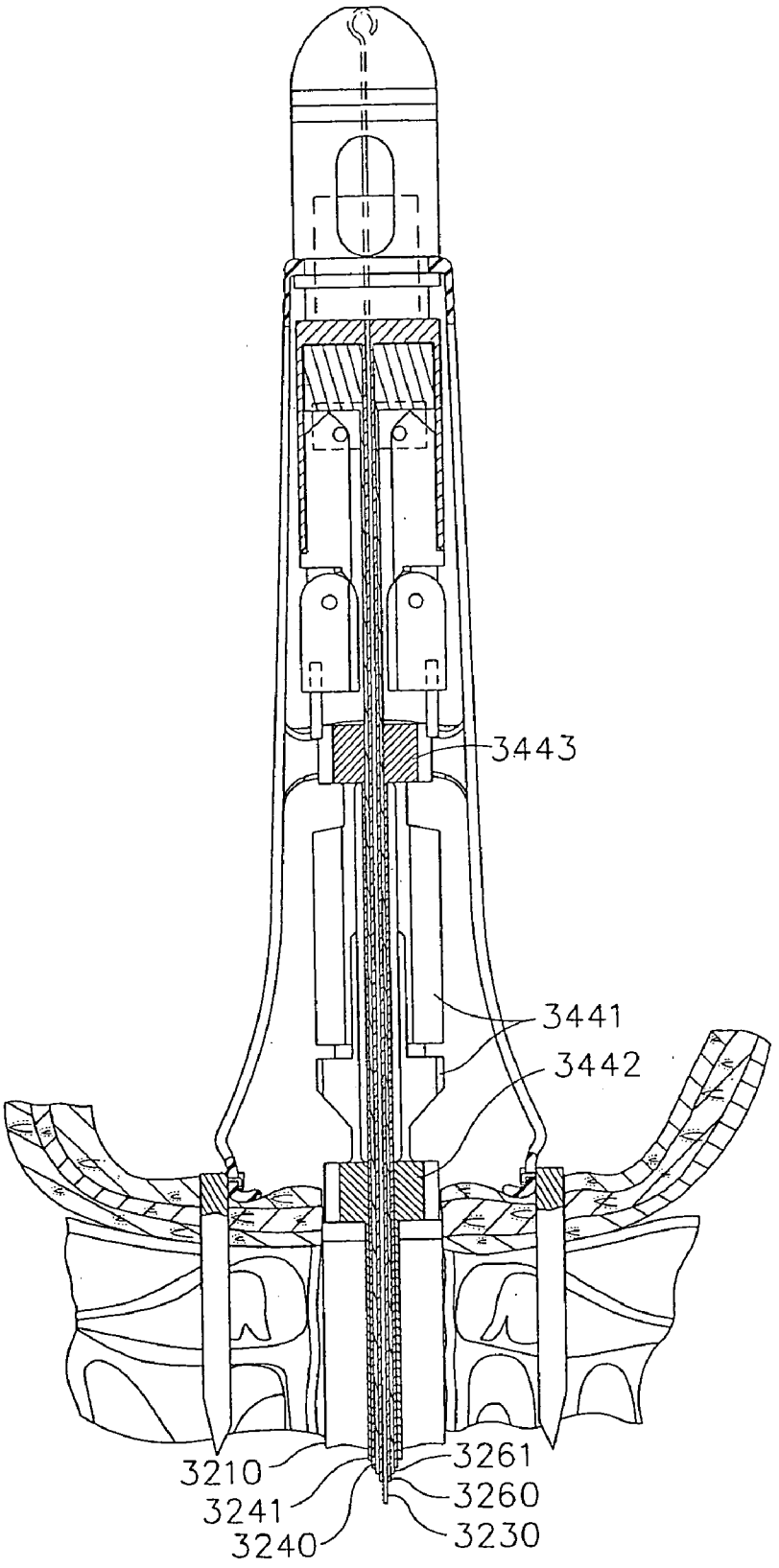

FIG. 140

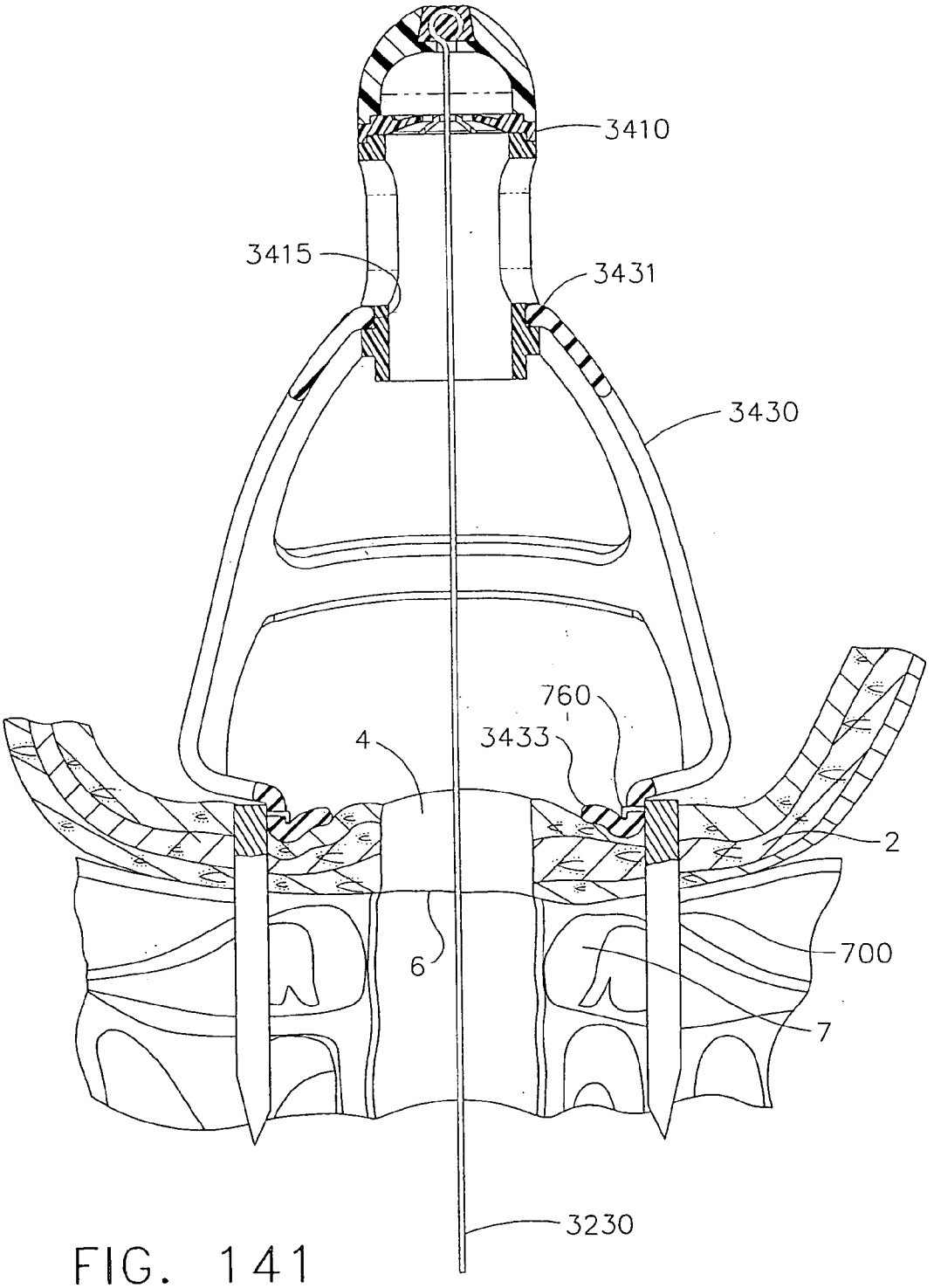

FIG. 141

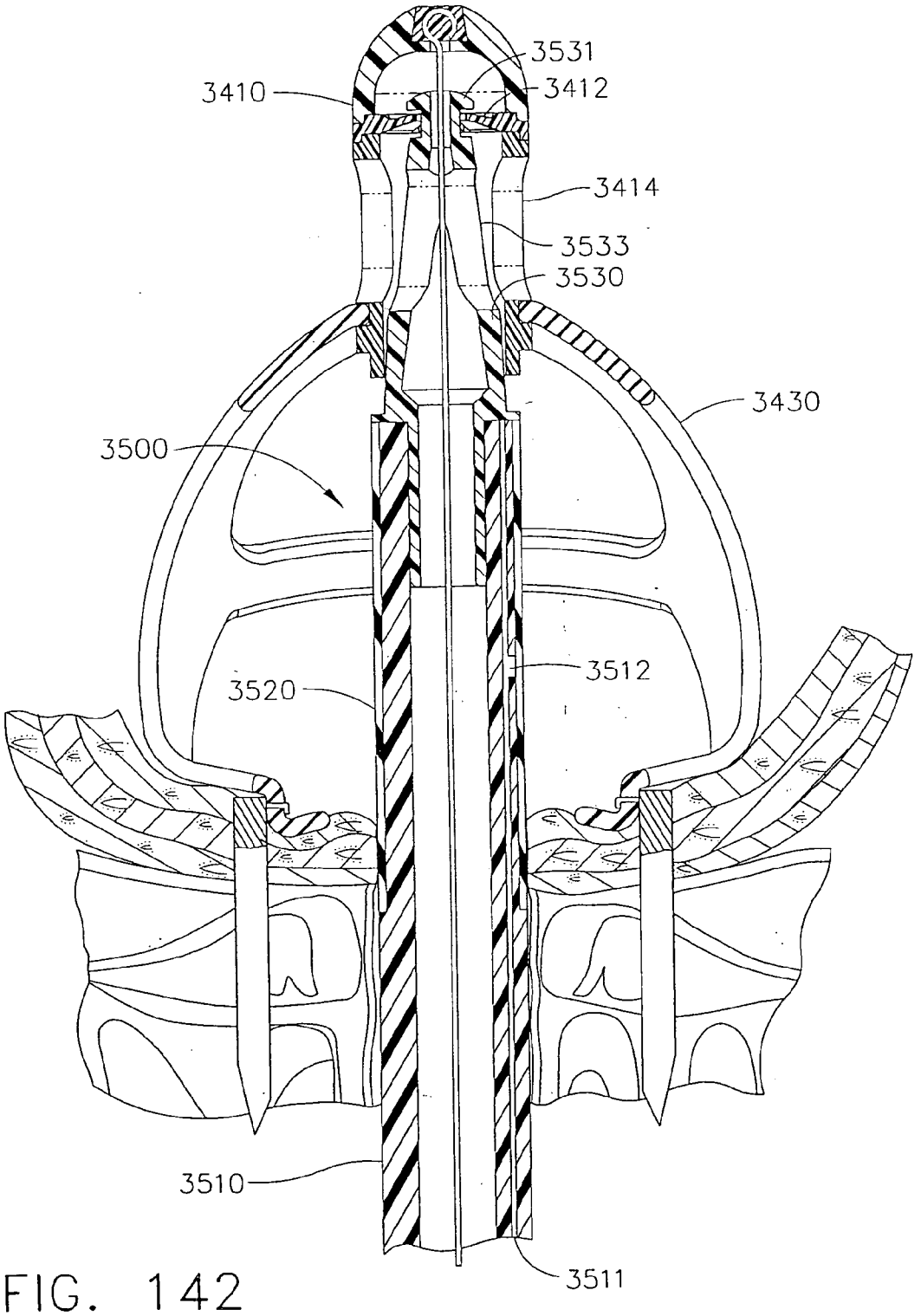

FIG. 142

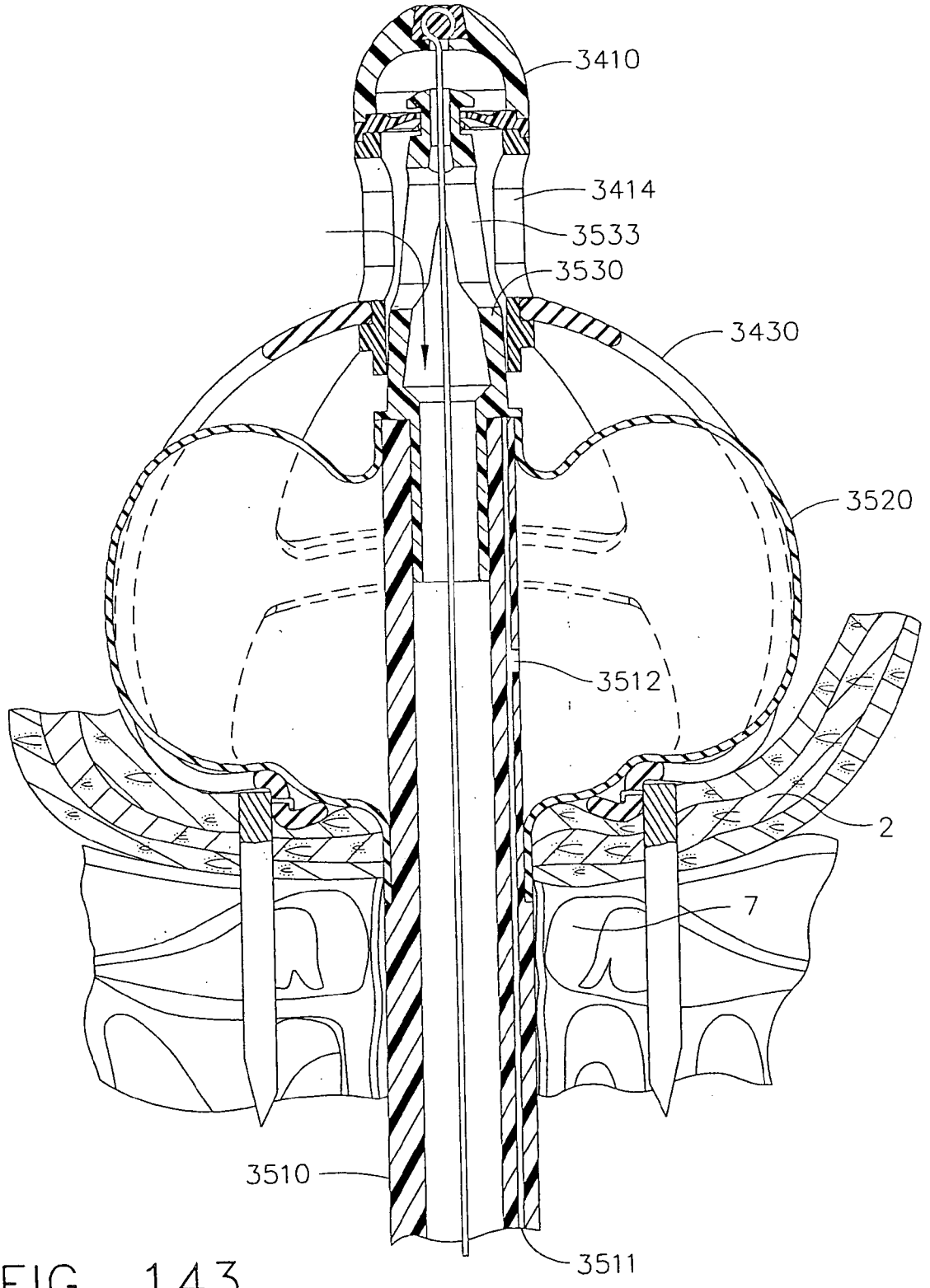

FIG. 143

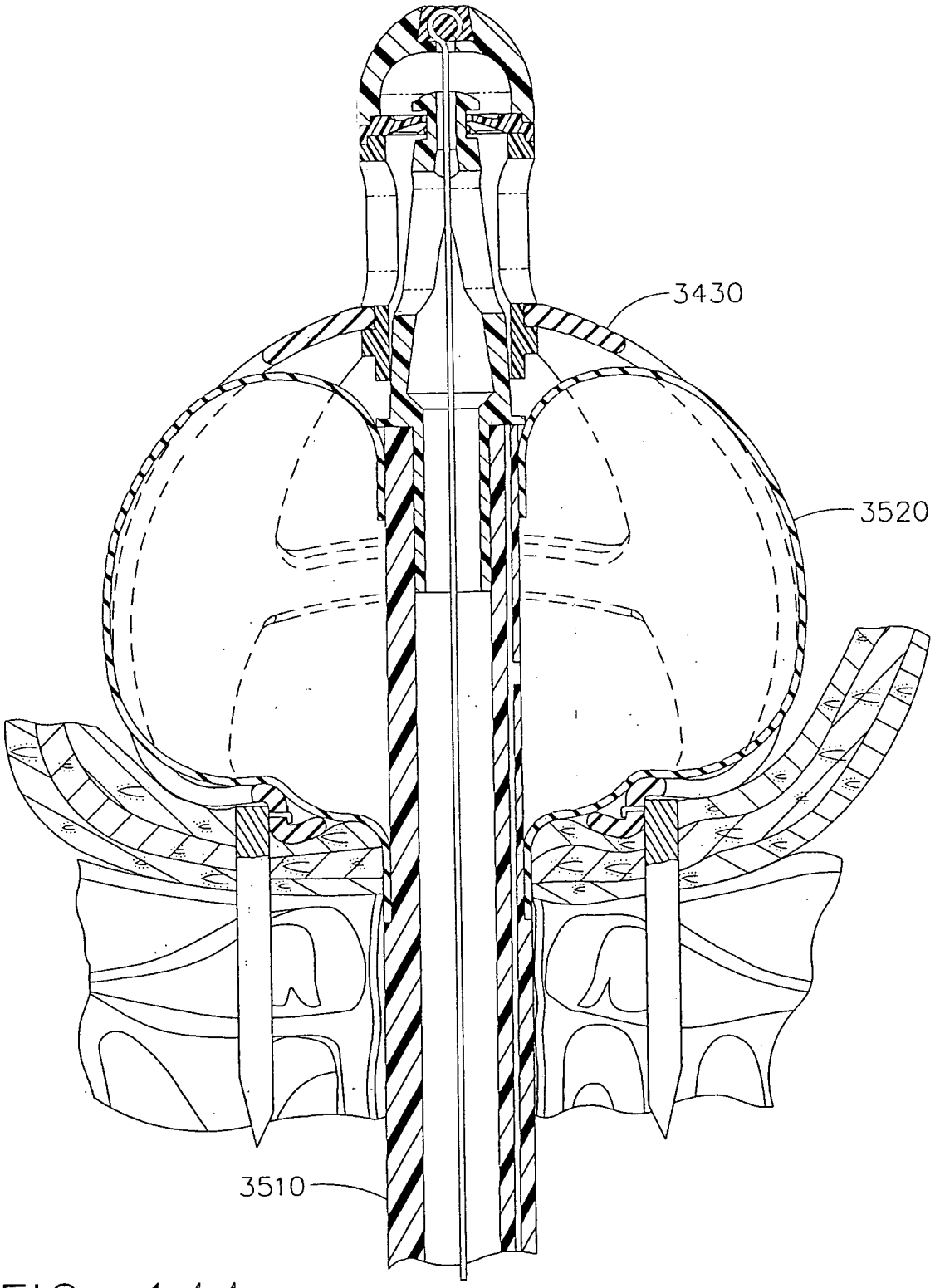

FIG. 144

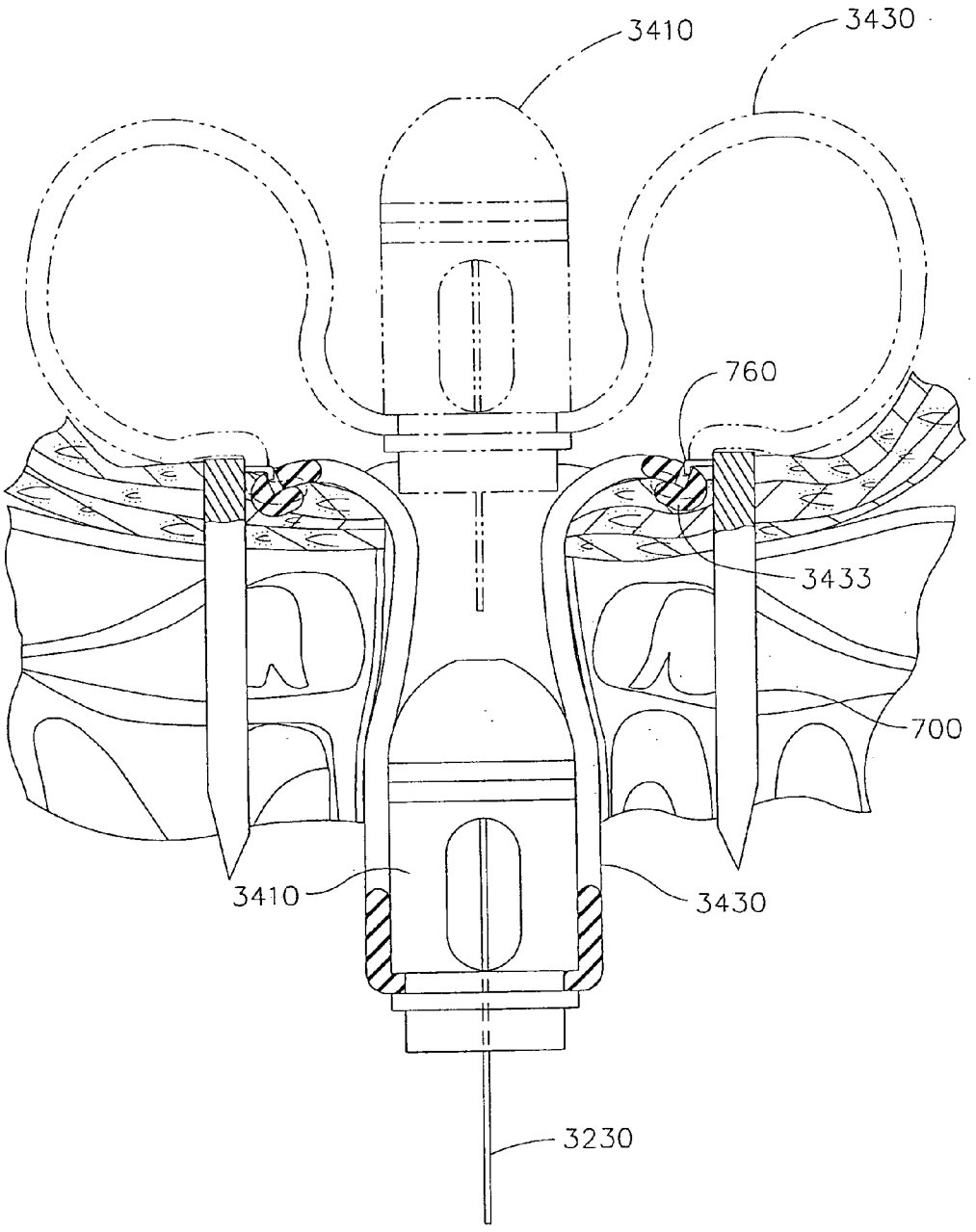

FIG. 145

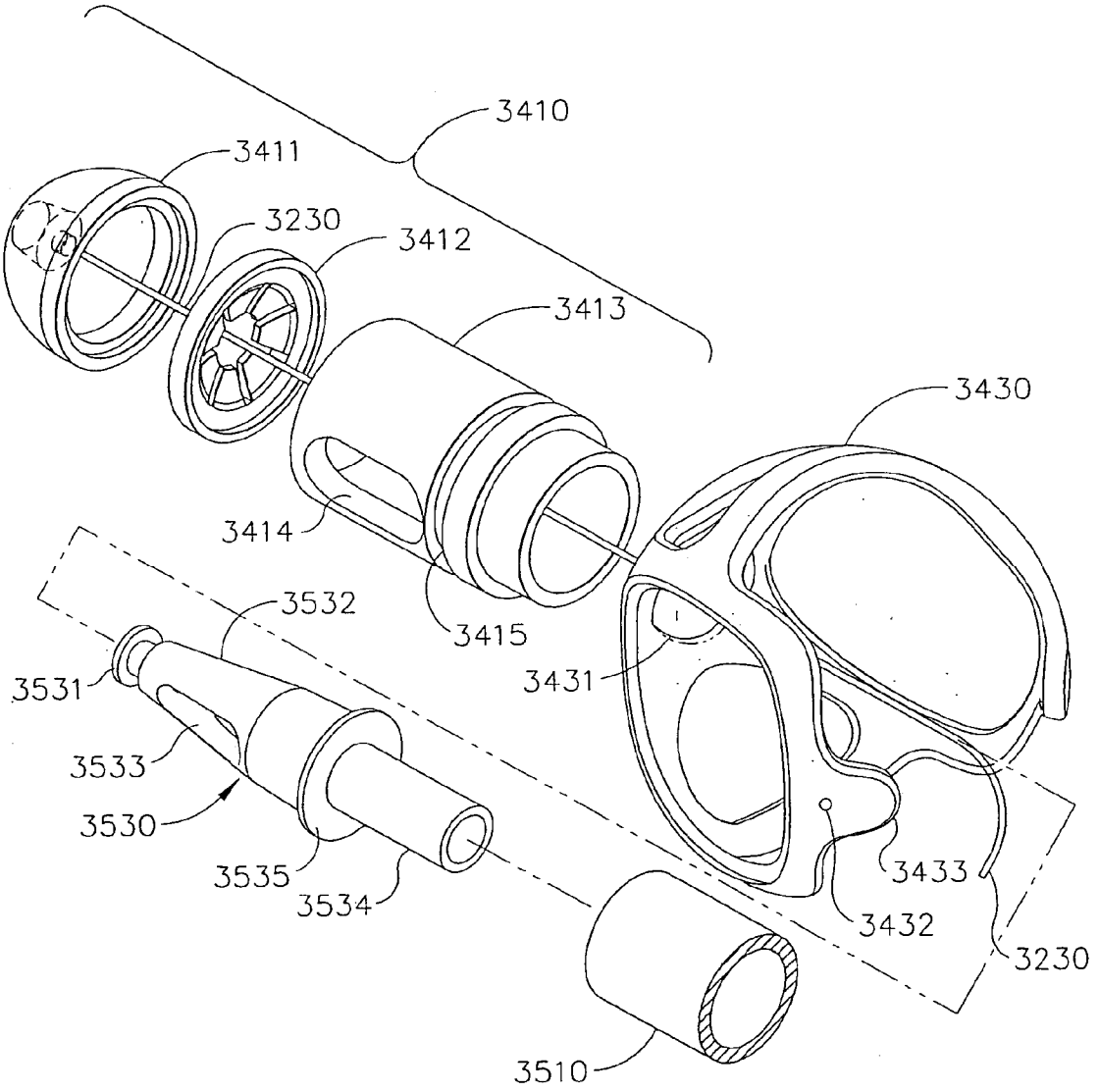
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FIG. 146

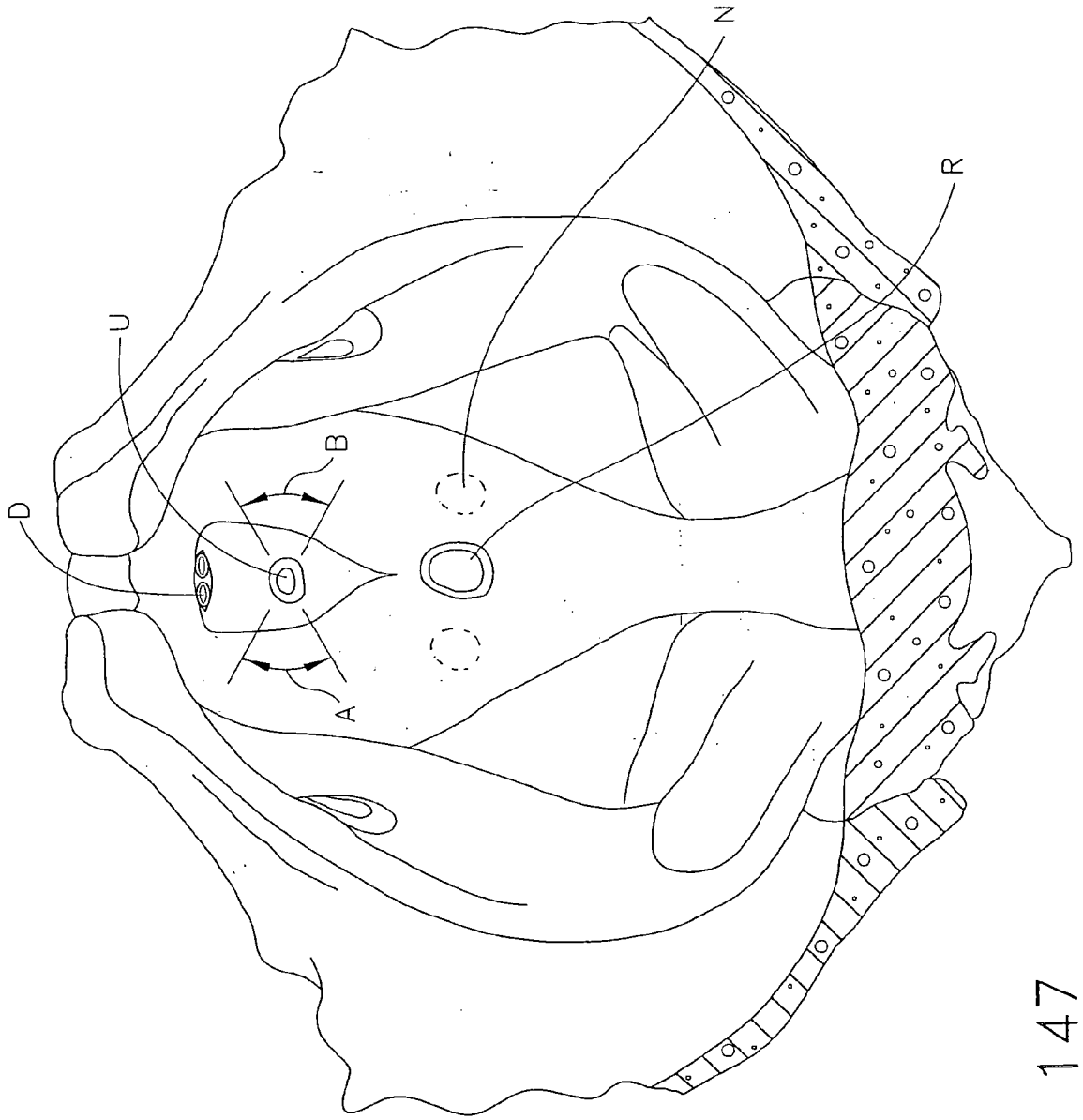

FIG. 147

DEVICE FOR ALTERNATELY HOLDING, OR EFFECTING RELATIVE LONGITUDINAL MOVEMENT, OF MEMBERS OF A MEDICAL INSTRUMENT

RELATED APPLICATIONS

[0001] This application claims the benefit of the filing date(s) of one or more of U.S. provisional applications: METHODS AND DEVICE FOR ANASTOMOSIS, Ser. No. 60/569,195, filed May 7, 2004; METHODS AND DEVICE FOR ANASTOMOSIS, Ser. No. 60/582,302, filed Jun. 23, 2004, and METHOD AND INSTRUMENT FOR EFFECTING ANASTOMOSIS OF RESPECTIVE TISSUES DEFINING TWO BODY LUMENS, Ser. No. 60/639,836, filed Dec. 28, 2004.

[0002] This application relates to and incorporates by reference in their entirety, for any and all purposes, the following non-provisional applications, filed substantially contemporaneously herewith and having one or more inventors in common with the instant application:

[0003] INSTRUMENT FOR EFFECTING ANASTOMOSIS OF RESPECTIVE TISSUES DEFINING TWO BODY LUMENS, Ser. No. (to be issued), filed Mar. 30, 2005;

[0004] METHOD AND INSTRUMENT FOR EFFECTING ANASTOMOSIS OF RESPECTIVE TISSUES DEFINING TWO BODY LUMENS, Ser. No. (to be issued), filed Mar. 30, 2005;

[0005] METHOD AND INSTRUMENT FOR EFFECTING ANASTOMOSIS OF RESPECTIVE TISSUES DEFINING TWO BODY LUMENS, Ser. No. (to be issued), filed Mar. 30, 2005;

[0006] INSTRUMENT FOR EFFECTING ANASTOMOSIS OF RESPECTIVE TISSUES DEFINING TWO BODY LUMENS, Ser. No. (to be issued), filed Mar. 30, 2005;

[0007] ANCHORS FOR USE IN ATTACHMENT OF BLADDER TISSUES TO PELVIC FLOOR TISSUES FOLLOWING A PROSTATECTOMY, Ser. No. (to be issued), filed Mar. 30, 2005;

[0008] INSTRUMENT FOR EFFECTING ANASTOMOSIS OF RESPECTIVE TISSUES DEFINING TWO BODY LUMENS, Ser. No. (to be issued), filed Mar. 30, 2005;

[0009] INSTRUMENT FOR EFFECTING ANASTOMOSIS OF RESPECTIVE TISSUES DEFINING TWO BODY LUMENS, Ser. No. (to be issued), filed Mar. 30, 2005;

[0010] METHOD AND INSTRUMENT FOR EFFECTING ANASTOMOSIS OF RESPECTIVE TISSUES DEFINING TWO BODY LUMENS, Ser. No. (to be issued), filed Mar. 30, 2005.

FIELD OF THE INVENTION

[0011] The present invention relates generally to the anastomosis of two hollow organs, a hollow organ and a vessel or two vessels, and is particularly directed to a method and embodiments of a device that accomplish the same in a minimally invasive manner. More particularly, the present invention also relates to an anastomosis instrument and method that may be used for the anastomosis of the bladder and urethra, especially after a patient's prostate has been removed in a prostatectomy.

BACKGROUND OF THE INVENTION

[0012] Prostate cancer is the second most common malignancy in males after cutaneous malignancies and is the second most common cause of cancer death among men in the United States. Prostate cancer is predominantly a disease of elderly men, and the absolute number of cases is expected to increase as worldwide life expectancy increases.

[0013] The retropubic approach to prostatectomy as a treatment for prostate cancer was introduced by Millin in 1947. The operation had distinct advantages over perineal prostatectomy in that urologists were more familiar with retropubic anatomy. The retropubic approach to radical prostatectomy also offers the advantage of the ability to perform an extraperitoneal pelvic lymph node dissection for staging purposes. During the past decade, modification in the technique of radical retropubic prostatectomy and the introduction of the anatomic nerve-sparing method resulted in a dramatic decrease in the two morbidities associated with the operation that cause the most concern—incontinence and impotence.

[0014] In a radical retropubic prostatectomy, the surgeon removes all or most of the patient's prostate. Because the urethra travels through the prostate, the upper part of the urethra is removed in the surgery. In order to restore proper urinary functions, the bladder and the urethra must be reconnected.

[0015] Providing this connection is particularly difficult due to the limited working space and the small size of the urethra. The size of the urethra makes it difficult to accurately place the suture thread through the wall of the urethra. Heretofore, surgeons would execute painstaking suturing operations with tiny, fine needles to reconnect the bladder to the urethra. It has been found that the use of sutures for this purpose has caused certain problems in recovery. These problems include necrosis of the sutured tissues, stricture of the urethra that impedes the flow of fluid through it, and a urethra-bladder connection that is not fluid-tight. In addition, when suturing the urethra to the bladder the surgeon can possibly inadvertently pierce the nearby neurovascular bundle, which can cause incontinence or impotence. The suturing process itself has also been found to be cumbersome, requiring the surgeon to grasp and stretch the bladder and urethra together before making the fine sutures. Sutures may also tear the urethra, resulting in further complications.

[0016] With radical retropubic prostatectomies becoming more common, faster and simpler ways to reconnect the bladder and urethra are in demand. It would be further advantageous to provide a means for the anastomosis of the urethra and bladder that does not require the use of potentially damaging sutures.

[0017] Additionally, there are other surgical procedures requiring the connection of vessels, hollow organs and tissues defining other body lumens. While some of these structures are large, and more easily manipulated by the surgeon, tissue structures defining other body lumens are smaller and more difficult to manipulate and hold in position while joining ends thereof after, for example, a transectional operation. Accordingly, a faster and simpler way to connect vessels, hollow organs and other tissues defining body lumens would be advantageous.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the present invention, and together with the description serve to explain the principles of the invention. In the drawings:

[0019] **FIG. 1** is a partial, vertical sectional schematic depiction of the positional relationships of the human male bladder, prostate and urethra, and surrounding pelvic floor, prior to a prostatectomy;

[0020] **FIG. 2** is a partial, vertical sectional schematic depiction of the positional relationships of the human male bladder and urethra, and surrounding pelvic floor, following a prostatectomy;

[0021] **FIG. 3** is a perspective view of an anastomotic instrument having an actuator handle, a driver assembly and a positioner assembly in accordance with one embodiment of the present invention;

[0022] **FIG. 4** is a longitudinal cross-sectional view of the actuator handle of the anastomotic instrument shown in **FIG. 3**;

[0023] **FIG. 5** is an expanded longitudinal cross-sectional view of the proximal end of the actuator handle of the anastomotic instrument shown in **FIG. 3**;

[0024] **FIG. 6** is an expanded longitudinal cross-sectional view of the distal end of the actuator handle of the anastomotic instrument shown in **FIG. 3**;

[0025] **FIG. 7** is a longitudinal cross-sectional view of the tube assembly, positioner assembly and driver assembly of the instrument shown in **FIG. 3**;

[0026] **FIG. 8** is an expanded longitudinal cross-sectional view of the bridge assembly portion of the tube assembly shown in **FIG. 7**;

[0027] **FIG. 9** is an expanded transverse cross-sectional view of the bridge assembly shown in **FIG. 8**;

[0028] **FIG. 10** is an expanded longitudinal cross-sectional view of the bridge assembly shown in **FIG. 8**;

[0029] **FIG. 11** is an expanded longitudinal cross-sectional view of a positioner assembly part of the anastomotic instrument shown in **FIG. 3**;

[0030] **FIG. 12** is a longitudinal cross-sectional view of the driver assembly part of the anastomotic instrument shown in **FIG. 3**;

[0031] **FIG. 13** is a perspective illustration of embodiments of the positioner and driver assemblies of the anastomotic instrument shown in **FIG. 3**;

[0032] **FIG. 14** is a perspective illustration of embodiments of the positioner and driver assemblies of the anastomotic instrument shown in **FIG. 3** with the positioner and driver assemblies shown in open positions;

[0033] **FIG. 15** is a cross-sectional overhead view of the positioner and driver assemblies of the anastomotic instrument shown in **FIG. 14** showing the driver arms and positioner arms in open positions;

[0034] **FIG. 16** is an expanded perspective view of the driver assembly of the anastomotic instrument shown in **FIG. 14**, showing driver arms, driver pins and anchors;

[0035] **FIG. 17** is a longitudinal cross-sectional view of another embodiment of an anastomotic instrument in accordance with the present invention;

[0036] **FIG. 18** is a transverse cross-sectional view of a driver assembly part of the anastomotic instrument shown in **FIG. 17**;

[0037] **FIG. 19** is a longitudinal cross-sectional view of the anastomotic instrument shown in **FIG. 17**, with driver and positioner petal assemblies shown in opened positions;

[0038] **FIG. 20** is a longitudinal cross-sectional view of the anastomotic instrument shown in **FIG. 17**, showing positioner petals in contact with tissue and anchor driver pins and anchors partially deployed into tissues;

[0039] **FIG. 21** is a longitudinal cross-sectional view of the anastomotic instrument shown in **FIG. 17**, showing positioner petals in contact with tissues and anchor driver pins and anchors driven into tissues;

[0040] **FIG. 22** is a longitudinal cross-sectional view of another alternate embodiment of an anastomotic instrument of the present invention;

[0041] **FIG. 23** is a cross-sectional view of the driver assembly part of the anastomotic instrument shown in **FIG. 22**;

[0042] **FIG. 24** is a longitudinal cross-sectional view of the anastomotic instrument shown in **FIG. 22**, with positioner petals shown in opened positions;

[0043] **FIG. 25** is a longitudinal cross-sectional view of the anastomotic instrument shown in **FIG. 22**, with positioner petals and a driver assembly shown in opened positions;

[0044] **FIG. 26** is a longitudinal cross-sectional view of the anastomotic instrument shown in **FIG. 22**, showing positioner petals in contact with tissue and anchor driver pins and anchors driven into tissues;

[0045] **FIG. 27** is an overhead view of the positioner assembly of the anastomotic instrument shown in **FIG. 24** with the driver assembly removed for purposes of illustration, showing the positioner petals in opened positions;

[0046] **FIG. 28** is a perspective illustration of the alternate anastomotic instrument shown in **FIG. 17**, shown in a closed position;

[0047] **FIG. 29** is a perspective illustration of the alternate anastomotic instrument shown in **FIG. 17**, shown in an opened position;

[0048] **FIG. 30** is a perspective illustration of the alternate anastomotic instrument shown in **FIG. 22**, shown in an opened position;

[0049] **FIG. 31** is an illustration of an anastomotic instrument fully inserted through a patient's urethra and into the bladder, following a prostatectomy;

[0050] **FIG. 32** is an illustration showing an anastomotic instrument fully inserted through a patient's urethra and into

the bladder following a prostatectomy, with driver and positioner assemblies opened;

[0051] **FIG. 33** is an illustration showing an anastomotic instrument fully inserted through a patient's urethra and into the bladder following a prostatectomy, with a positioner assembly urging the bladder wall into contact with the pelvic floor with the openings in the bladder and urethra aligned;

[0052] **FIG. 34** is an illustration showing an anastomotic instrument fully inserted through a patient's urethra and into the bladder following a prostatectomy, and with a driver assembly actuated and anchors driven through the bladder wall and into the pelvic floor;

[0053] **FIG. 35** is an illustration showing an anastomotic instrument inserted through the urethra and into the bladder, with a driver assembly and driver pins retracted and withdrawn from anchors, which are left installed through the bladder wall and into the pelvic floor;

[0054] **FIG. 36** is an illustration showing an anastomotic instrument fully inserted through a patient's urethra and into the bladder following a prostatectomy, with driver and positioner assemblies returned to initial retracted positions following installation of anchors;

[0055] **FIG. 37** is an illustration showing the bladder and urethra after installation of anchors and removal of an anastomotic instrument used to effect such installation, and showing a guide wire left in place for guiding a catheter into the bladder through the urethra;

[0056] **FIG. 38** is a schematic illustration showing the bladder and urethra after installation of anchors and removal of an anastomotic instrument used to effect such installation, and showing a balloon catheter system inserted into the bladder through the urethra and leading to a urine collection bag;

[0057] **FIG. 39** is a perspective illustration of an embodiment of an anchor;

[0058] **FIG. 40** is a perspective illustration of an alternate embodiment of an anchor;

[0059] **FIG. 41** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0060] **FIG. 42** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0061] **FIG. 43** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0062] **FIG. 44** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0063] **FIG. 45** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0064] **FIG. 46** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0065] **FIG. 47** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0066] **FIG. 48** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0067] **FIG. 49** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0068] **FIG. 50** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0069] **FIG. 51** is a perspective illustration of an alternate embodiment of an anchor shaft and tip;

[0070] **FIG. 52** is a schematic illustration of a driving button assembly shown in a cocked position;

[0071] **FIG. 53** is a schematic illustration of a driving button assembly shown in a released position;

[0072] **FIG. 54** is a schematic illustration of a driving button assembly shown in a forward seating position;

[0073] **FIG. 55** is a perspective view of an embodiment of an antegrade vesico urethral anastomosis instrument in accordance with the present invention;

[0074] **FIG. 56** is a partial view of the instrument shown in **FIG. 55**, including a curved tube assembly and anastomosis end effector, inserted into the bladder of a patient as used in accordance with the present invention;

[0075] **FIG. 57** is a partial view of the instrument shown in **FIG. 55**, including an opened positioner assembly as used in accordance with the present invention;

[0076] **FIG. 58** is a partial view of the instrument shown in **FIG. 55**, including an opened anchor assembly as used in accordance with the present invention;

[0077] **FIG. 59** is a partial view of the instrument shown in **FIG. 55**, showing positioner arms urging the bladder wall into contact with the pelvic floor in accordance with the present invention;

[0078] **FIG. 60** is a partial view of the instrument shown in **FIG. 55**, after anchors have been driven through the bladder wall into the pelvic floor in accordance with the present invention;

[0079] **FIG. 61** is a partial view of the instrument shown in **FIG. 55**, following withdrawal of anchor driver pins from installed anchors in accordance with the present invention;

[0080] **FIG. 62** is a partial view of the instrument shown in **FIG. 55**, after partial retraction of the instrument to unfold a harness in accordance with the present invention;

[0081] **FIG. 63** is a partial view of the instrument shown in **FIG. 55**, following closing of an anchor assembly and positioner assembly in preparation for their withdrawal, to leave a balloon assembly and catheter behind in accordance with the present invention;

[0082] **FIG. 64** is a partial view of the instrument shown in **FIG. 55**, after removal of a positioner assembly and anchor assembly, used in accordance with the present invention, has commenced;

[0083] **FIG. 65** is a partial view of the instrument shown in **FIG. 55**, after removal of a positioner assembly and anchor assembly, and after inflation of a balloon secured with an anchored harness, used in accordance with the present invention;

[0084] **FIG. 66** is a perspective view of a harness portion of the instrument shown in **FIG. 55**, as it may be secured to anchors via harness anchoring loops;

[0085] **FIG. 67** is a longitudinal cross-sectional view of an embodiment of a balloon assembly that may be adapted for use in accordance with the present invention;

[0086] **FIG. 68** is a transverse cross-sectional view of a catheter that may be used in accordance with the present invention;

[0087] **FIG. 69** is a longitudinal cross-sectional view of one embodiment of a catheter cap and a urine collection bag that may be used in accordance with the present invention;

[0088] **FIG. 70** is an exploded view of an embodiment of an end effector assembly of the instrument shown in **FIG. 55**;

[0089] **FIG. 71** is a longitudinal and perspective sectional, partial view of an embodiment of an end effector assembly of the instrument shown in **FIG. 55**, showing an open anchor assembly and partially open positioner assembly;

[0090] **FIG. 72** is a longitudinal and perspective sectional view of a transitional tube portion of an anastomosis instrument such as shown in **FIG. 55**, showing exemplary linkages for actuator tubes;

[0091] **FIG. 73** is a longitudinal cross-sectional view of a closing tube latching collar portion of the instrument shown in **FIG. 55**, in a closed position;

[0092] **FIG. 74** is a longitudinal cross-sectional view of a closing tube latching collar portion of the instrument shown in **FIG. 55**, in an open position;

[0093] **FIG. 75** is a side cross-sectional view of an embodiment of a handle assembly of the instrument shown in **FIG. 55**;

[0094] **FIG. 76** is an exploded perspective view of the handle assembly shown in **FIG. 75**;

[0095] **FIG. 77** is a sectional view of a positioner assembly and connected portions of the handle assembly shown in **FIG. 55**, showing the components involved in the operation of the positioner assembly;

[0096] **FIG. 78** is a perspective view of a positioner assembly of the instrument shown in **FIG. 55**, shown partially open;

[0097] **FIG. 79** is a sectional view of an anchor assembly and connected portions of the handle assembly shown in **FIG. 55**, showing the components involved in opening and closing the anchor assembly;

[0098] **FIG. 80** is an exploded perspective view of a closing tube latching collar, and associated components, of the instrument shown in **FIG. 55**;

[0099] **FIG. 81** is a sectional view of an anchor assembly and connected portions of the handle assembly shown in **FIG. 55**, showing the components involved in driving anchors;

[0100] **FIG. 82** is a sectional view of a curved spine tube and connected portions of the handle assembly shown in **FIG. 55**, showing a fixed, skeletal structure of the instrument;

[0101] **FIG. 83** is a perspective view of the distal and proximal ends of another embodiment of an anastomotic instrument of the present invention, shown in a retracted, pre-deployment position, with the intermediate section removed for ease of depiction in the drawing;

[0102] **FIG. 84** is a longitudinal cross section of the distal end of the instrument shown in **FIG. 83**, shown in a retracted, pre-deployment position;

[0103] **FIG. 85** is a longitudinal cross section of an embodiment of a handle assembly adapted for use at the proximal end of an anastomotic instrument of the present invention;

[0104] **FIG. 86** is a partial transverse cross section of the instrument shown in **FIG. 84**, indicated at **86-86** of **FIG. 84**, showing sectional views of an outer driver assembly tube, anchor driver pin, inner driver assembly tube, positioner tube, and anchor, loaded into the instrument in a pre-deployment position;

[0105] **FIG. 87** is a side view of a forward member of an anchor that may be used with the instrument shown in **FIG. 83**, shown in a pre-deployment position as in contact with an anchor driver pin;

[0106] **FIG. 88** is a longitudinal cross section of the instrument shown in **FIG. 83**, shown in a retracted, pre-deployment position after insertion into and through a patient's urethra and into the bladder, following a prostatectomy;

[0107] **FIG. 89** is a longitudinal cross section of the instrument shown in **FIG. 83**, shown after insertion into and through a patient's urethra and into the bladder, and after a positioner has been moved to a deployed position;

[0108] **FIG. 90** is a longitudinal cross section of an embodiment of the instrument shown in **FIG. 83**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, and after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned;

[0109] **FIG. 91** is a longitudinal cross section of the instrument shown in **FIG. 83**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, and after actuation of an anchor driver assembly to drive anchors into the tissues of the pelvic floor and bladder wall, surrounding the aligned urethra opening and bladder opening;

[0110] **FIG. 92** is a longitudinal cross section of the instrument shown in **FIG. 83**, shown after insertion into and through the urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, after anchors have been installed, and after retraction of an anchor driver assembly has commenced, to leave a positioner and positioner tube behind to enable draining of urine from the bladder during recovery and healing;

[0111] **FIG. 93** is a longitudinal cross section of another alternative embodiment of an anastomotic instrument of the present invention, shown after a positioner has been moved to a deployed position, comprising an alternative configuration of driver pins and an outer driver assembly tube;

[0112] **FIG. 94** is a longitudinal cross section of another alternative embodiment of an anastomotic instrument of the present invention, shown after a positioner has been moved to a deployed position, comprising an alternative configuration of driver pins and an outer driver assembly tube, and showing an alternative pre-deployment orientation of rearward members and connecting members of anchors;

[0113] **FIG. 95** is a perspective view of the distal and proximal ends of another embodiment of an anastomotic instrument in accordance with the present invention, shown in a retracted, pre-deployment position, with the intermediate section removed for ease of depiction in the drawing;

[0114] **FIG. 96** is a longitudinal cross section of the distal end of the instrument shown in **FIG. 95**, shown in a retracted, pre-deployment position;

[0115] **FIG. 97** is a partial transverse cross section of the instrument shown in **FIG. 96**, indicated at **97-97** of **FIG. 96**, showing sectional views of a second anchor guide collar, first anchor guide collar, positioner tube, and a first anchor and trailing suture, loaded into the instrument in pre-deployment positions;

[0116] **FIG. 98** is a partial transverse cross section of the instrument shown in **FIG. 96**, indicated at **98-98** of **FIG. 96**, showing sectional views of an outer driver assembly tube, anchor guide collar, anchor driver pin, inner driver assembly tube, positioner tube, and second anchor and an end of a trailing suture, loaded into the instrument in pre-deployment positions;

[0117] **FIG. 99** is an enlarged perspective view of an embodiment of a first anchor that may be used in the instrument shown in **FIG. 95**, shown in a deployed shape;

[0118] **FIG. 100** is an enlarged frontal view of an embodiment of a second anchor that may be used in the instrument shown in **FIG. 95**, shown in a deployed shape;

[0119] **FIG. 101** is an enlarged side view of the second anchor shown in **FIG. 100**;

[0120] **FIG. 102** is a longitudinal cross section of the instrument shown in **FIG. 95**, shown in a retracted, pre-deployment position after insertion into and through a patient's urethra and into the bladder, following a prostatectomy;

[0121] **FIG. 103** is a longitudinal cross section of the instrument shown in **FIG. 95**, shown after insertion into and through a patient's urethra and into the bladder, and after a positioner has been moved to a deployed position;

[0122] **FIG. 104** is a longitudinal cross section of the instrument shown in **FIG. 95**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, and after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned;

[0123] **FIG. 105** is a longitudinal cross section of the instrument shown in **FIG. 95**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, and after a first actuation of an anchor driver assembly to drive first anchors into the tissues of the bladder wall surrounding the bladder opening;

[0124] **FIG. 106** is a longitudinal cross section of the instrument shown in **FIG. 95**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, after a first actuation of an anchor driver assembly to drive first anchors into the tissues of the bladder wall surrounding the bladder opening, and after repositioning of anchor driver pins in preparation to drive second anchors;

[0125] **FIG. 107** is a longitudinal cross section of the instrument shown in **FIG. 95**, shown after insertion into and through a patient's urethra and into the bladder, after the positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, after a first actuation of an anchor driver assembly to drive first anchors into the tissues of the bladder wall surrounding the bladder opening, and after a second actuation of an anchor assembly to drive second anchors into the tissues surrounding the urethra opening;

[0126] **FIG. 108** is a longitudinal cross section of the instrument shown in **FIG. 95**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, after anchor pairs and connecting sutures have been installed, and after retraction of an anchor driver assembly has commenced, to leave the positioner and a positioner tube behind to enable draining of urine and other fluids from the bladder during recovery and healing;

[0127] **FIG. 109** is a longitudinal cross section of the instrument shown in **FIG. 95**, shown after retraction of an anchor driver assembly and after the anastomosis procedure has been completed, with a positioner in a retracted position ready for withdrawal of the remaining parts of the instrument from the bladder, down through the urethra and out of the patient's body;

[0128] **FIG. 110** is a perspective view of another embodiment of the distal and proximal ends of an anastomotic instrument of the present invention, with the intermediate section removed for ease of depiction in the drawing;

[0129] **FIG. 111** is a longitudinal cross section of the instrument shown in **FIG. 110**, shown in a retracted and pre-deployment position after insertion into and through a patient's urethra and into the bladder, following a prostatectomy;

[0130] **FIG. 112** is a longitudinal cross section of the instrument shown in **FIG. 110**, shown after insertion into and through a patient's urethra and into the bladder, and after a positioner has been moved to a deployed position;

[0131] **FIG. 113** is a longitudinal cross section of the instrument shown in **FIG. 110**, shown after insertion into and through the urethra and into the bladder, after a positioner has been moved to a deployed position, and after an expander collar has been drawn into a fastener driver assembly to expand a fastener set;

[0132] **FIG. 114** is a longitudinal cross section of the instrument shown in **FIG. 100**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after an expander collar has been drawn into a fastener driver assembly to expand a fastener set, and after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned;

[0133] **FIG. 115** is a longitudinal cross section of the instrument shown in **FIG. 110**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, and after actuation of a fastener driver assembly has begun;

[0134] **FIG. 116** is a longitudinal cross section of the instrument shown in **FIG. 110**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, and after a fastener driver assembly has been fully actuated to install a fastener set;

[0135] **FIG. 117** is a longitudinal cross section of the instrument shown in **FIG. 110**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, after a fastener driver assembly has been fully actuated to install a fastener set, and after an expander collar has been moved out of the fastener driver assembly to allow the fastener driver assembly to assume a smaller diameter which will allow it to be retracted through the installed fastener set;

[0136] **FIG. 118** is a longitudinal cross section of the instrument shown in **FIG. 110**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, after a fastener set has been installed, and after a fastener driver assembly has been withdrawn from the patient to leave the positioner and a positioner tube behind to enable draining of urine and other fluids from the bladder during recovery and healing;

[0137] **FIG. 119** is an enlarged perspective view of a fastener set that may be used with the instrument shown in **FIG. 110**, shown in the shape it may have prior to expansion and installation;

[0138] **FIG. 120** is an enlarged perspective view of a fastener set that may be used with the instrument shown in **FIG. 110**, shown in the shape may have after expansion and installation;

[0139] **FIG. 121** is an enlarged perspective view of an end cap of an actuator rod that may be used with the instrument shown in **FIG. 110**;

[0140] **FIG. 122** is a longitudinal cross section of another embodiment of an anastomotic instrument of the present invention, in a pre-deployment, retracted position;

[0141] **FIG. 123** is a longitudinal cross section of the instrument shown in **FIG. 122**, shown after insertion into and through a patient's urethra and into the bladder, following a prostatectomy;

[0142] **FIG. 124** is a longitudinal cross section of the instrument shown in **FIG. 122**, shown after insertion into and through a patient's urethra and into the bladder, and after a positioner has been moved to a deployed position;

[0143] **FIG. 125** is a longitudinal cross section of the instrument shown in **FIG. 122**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, and after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned;

[0144] **FIG. 126** is a longitudinal cross section of the instrument shown in **FIG. 122**, shown after insertion into and through a patient's urethra and into the bladder, after a positioner has been moved to a deployed position, after the bladder wall has been urged into contact with the pelvic floor with the openings in the bladder and urethra aligned, and after a lodging member has been moved to a deployed position;

[0145] **FIG. 127** is an enlarged perspective view of an end cap of a positioner actuating rod, that may be used with the instrument shown in **FIG. 122**;

[0146] **FIG. 128** is a schematic view of the instrument shown in **FIG. 122**, shown inserted into a patient with a positioner in a deployed position, with the instrument connected at its proximal end to a urine collection bag;

[0147] **FIG. 129** is a longitudinal cross section of another embodiment of the instrument of the present invention, configured for an antegrade anastomosis procedure, shown in a deployed position;

[0148] **FIG. 130** is a longitudinal cross section of another embodiment of the instrument of the present invention, configured for an antegrade anastomosis procedure, shown in a deployed position;

[0149] **FIG. 131** is a perspective view of an embodiment of a lodging member having perforations and projections;

[0150] **FIG. 132** is a longitudinal cross section of the lodging member shown in **FIG. 131**;

[0151] **FIG. 133** is a longitudinal cross section of another embodiment of a lodging member having perforations and projections;

[0152] **FIG. 134** is a perspective view of an anastomotic instrument having an actuator handle, a tube assembly and an end effector assembly in accordance with one embodiment of the present invention;

[0153] **FIG. 135** is a longitudinal cross-sectional view of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder opening;

[0154] **FIG. 136** is a longitudinal cross-sectional view of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder lumen, with a positioner assembly and an anchor

driver assembly opened, and with the positioner assembly urging the bladder wall into contact with the pelvic floor;

[0155] **FIG. 137** is a longitudinal cross-sectional view of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder lumen, with a positioner assembly opened, and after a driver assembly has driven anchors through the bladder wall and into the pelvic floor;

[0156] **FIG. 138** is a longitudinal cross-sectional view of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder lumen, with a positioner assembly opened, after a driver assembly has driven anchors through the bladder wall and into the pelvic floor, and after driver pins have been withdrawn from the anchors;

[0157] **FIG. 139** is a longitudinal cross-sectional view of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder lumen, with a positioner assembly opened, after a driver assembly has driven anchors through the bladder wall and into the pelvic floor, after driver pins have been withdrawn from anchors driven into the pelvic floor, and after the driver assembly has been closed;

[0158] **FIG. 140** is a longitudinal cross-sectional view of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder lumen, with a positioner assembly opened, after a driver assembly has driven anchors through the bladder wall and into the pelvic floor, after driver pins have been withdrawn from anchors driven into the pelvic floor, and after the driver assembly and positioner assembly have been closed;

[0159] **FIG. 141** is a longitudinal cross-sectional view of components of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder lumen, after installation of anchors, and after positioner and anchor driver assemblies have been withdrawn to leave behind an end cap assembly, anchors installed through the bladder wall and into the pelvic floor, and a balloon harness attached therebetween;

[0160] **FIG. 142** is a longitudinal cross-sectional view of components of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder lumen, after installation of anchors, after positioner and anchor driver assemblies have been withdrawn to leave behind an end cap assembly, anchors installed through the bladder wall and into the pelvic floor, and a balloon harness attached therebetween, and after insertion of a balloon catheter assembly;

[0161] **FIG. 143** is a longitudinal cross-sectional view of components of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder lumen, after installation of anchors, after positioner and anchor driver assemblies have been withdrawn to leave behind an end cap assembly, anchors installed through the bladder wall and into the pelvic floor, and a balloon harness attached therebetween, after insertion of a balloon catheter assembly, and after inflation of a balloon;

[0162] **FIG. 144** is a longitudinal cross-sectional view of components of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown inserted into and through a patient's urethra and into the bladder lumen, after installation of anchors, after positioner and anchor driver assemblies have been withdrawn to leave behind an end cap assembly, anchors installed through the bladder wall and into the pelvic floor, and a balloon harness attached therebetween, after insertion of a balloon catheter assembly, and after inflation of a balloon, shown one possible alternative embodiment;

[0163] **FIG. 145** is a longitudinal cross-sectional view of components of an end effector assembly of an anastomotic instrument in accordance with one embodiment of the present invention, shown after the anastomosis procedure has been substantially completed, after withdrawal of a balloon catheter assembly, and in successive positions during withdrawal of an end cap assembly and balloon harness;

[0164] **FIG. 146** is a perspective, exploded view of exemplary embodiments of an end cap assembly, balloon harness, and catheter end plug portion of a balloon catheter assembly; and

[0165] **FIG. 147** is a transverse (horizontal), superior (top) partial planar view of the human male pelvis and pelvic floor architecture, depicting preferred locations for installation of anchors.

[0166] Reference will now be made in detail to various alternative embodiments of the method and instrument of the invention, and various alternative components thereof, illustrated in the accompanying drawings.

DETAILED DESCRIPTION OF THE INVENTION

[0167] Before the present method and embodiments of an instrument are disclosed and described, it is to be understood that this invention is not limited to the particular process steps and materials disclosed herein as such process steps and materials may vary somewhat. It is also to be understood that the terminology used herein is used for the purpose of describing particular embodiments only and is not intended to be limiting since the scope of the present invention will be limited only by the appended claims.

[0168] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs. Although any method, instrument and materials similar or equivalent to those described herein may be used in the practice or testing of the invention, particular embodiments of a method, instrument and materials are now described.

[0169] It must be noted that, as used in this specification and the appended claims, the singular forms "a,""an," and "the" include plural referents unless the content clearly dictates otherwise.

[0170] In describing and claiming the present invention, the following terminology will be used in accordance with the definitions set out below.

[0171] As used herein, the term "anastomosis" means the surgical joining of respective tissues defining body lumens and other hollow body structures, especially the joining of hollow vessels, passageways or organs to create an intercommunication between them.

[0172] The term "patient," used herein, refers to any human or animal on which an anastomosis may be performed.

[0173] As used herein, the term "biocompatible" includes any material that is compatible with the living tissues and system(s) of a patient by not being substantially toxic or injurious and not causing immunological rejection. "Biocompatibility" includes the tendency of a material to be biocompatible.

[0174] As used herein, the term "bioabsorbable" includes the ability of a material to be dissolved and/or degraded, and absorbed, by the body.

[0175] As used herein, the term "shape memory" includes the tendency of a material, such as but not limited to a suitably prepared nickel-titanium alloy ("nitinol"), to return to a preformed shape, following deformation from such shape.

[0176] As used herein, the term "integral" means that two or more parts so described are affixed, fastened or joined together so as to move or function together as a substantially unitary part. "Integral" includes, but is not limited to, parts that are continuous in the sense that they are formed from the same continuous material, but also includes discontinuous parts that are joined, fastened or affixed together by any means so as become substantially immovably affixed to, and substantially unitary with, each other.

[0177] As used herein, the term "proximal" (or any form thereof), with respect to a component of an instrument, means that portion of the component that is generally nearest the surgeon, or nearest to the end of the instrument handled by the surgeon, when in use; and with respect to a direction of travel of a component of an instrument, means toward the end of the instrument generally nearest the surgeon, or handled by the surgeon, when in use.

[0178] As used herein, the term "distal" (or any form thereof), with respect to a component of an instrument, means that portion of the component that is generally farthest from the surgeon, or farthest from the end of the instrument handled by the surgeon, when in use; and with respect to a direction of travel of a component of an instrument, means away from the end of the instrument generally nearest the surgeon, or handled by the surgeon, when in use.

[0179] As used herein, the term "transverse" (or any form thereof), with respect to an axis, means extending in a line, plane or direction that is across such axis, i.e., not collinear or parallel therewith. "Transverse" as used herein is not to be limited to "perpendicular".

[0180] As used herein, the term "longitudinal axis", with respect to an instrument, means the exact or approximate central axis defined by said instrument along its greater dimension, i.e., along its length, from its distal end to its proximal end, and vice versa, and is not intended to be limited to imply a straight line, wherein, for example, an instrument includes a bend angle as described herein, it is intended that "longitudinal axis" as used herein follows such bend angle. Where used in association with an end effector, the term "longitudinal axis" means the exact or approximate central axis defined by said end effector extending along its greater dimension, i.e., along its length, from its distal end to its proximal end, and vice versa.

[0181] The method and instrument of the present invention utilizes a simple, effective mechanical arrangement for performing anastomosis of respective tissues defining two body lumens, for example, connecting the bladder to the urethra following a prostatectomy. By eliminating more painstaking, cumbersome suturing techniques, anastomosis techniques are improved. For use in the disclosed procedure, there are provided various embodiments of an improved instrument for bringing bladder wall tissues into contact with the pelvic floor tissues, with the openings in the bladder and urethra aligned, and for securing them in position so that they may knit and heal together.

[0182] By utilizing the disclosed techniques and an instrument of the present invention, the number of steps in the anastomosis procedure may be decreased, decreasing cost and reducing the required time for the procedure. The present invention may also eliminate complications associated with other anastomosis techniques that require hand suturing.

[0183] The present invention provides for a system that allows for, for example, connecting the bladder to the urethra using an instrument inserted through the urethra and into the bladder (in retrograde direction) without the need for access inside the bladder for manipulation and actuation of the instrument. Alternatively, the system and instrument may be configured such that it may be inserted into the bladder and then the urethra in an antegrade direction, through small incisions in the patient's abdomen and an upper surface of the bladder. Again, manipulation and actuation of the instrument may be performed by the surgeon from outside the patient's body.

[0184] Referring now to the drawings in detail, wherein like numerals indicate the same elements throughout the views, **FIG. 1** schematically illustrates in vertical cross section the positioning of a human male bladder **1**, bladder wall **2**, prostate **3**, pelvic floor **7** and urethra **5**, prior to a prostatectomy. In a radical prostatectomy, the prostate **3**, a lower portion of the bladder wall **2**, and an upper portion of the urethra **5** are excised, removing the fluid connection between the bladder lumen **8** and the remaining portion of the urethra. The substantially horizontal broken lines in **FIG. 1** schematically illustrate the lines along which the prostate and adjacent bladder and urethra tissues are excised.

[0185] **FIG. 2** depicts an anatomical cross-section of the abdominal cavity following a radical prostatectomy wherein the excision of a portion of the bladder wall **2** results in a bladder opening **4** and the excision of the prostate results in a urethra opening **6** in urethra **5**. Following this surgery, bladder opening **4** is typically reduced in size by means known in the art, such as a "tennis racket" suture technique.

Rotationally-Opened Embodiment

[0186] **FIGS. 3-16** show an embodiment of an instrument **10** which may be used to perform an anastomosis procedure, for example, a procedure to effect anastomosis of a patient's bladder and urethra following a prostatectomy.

[0187] As shown configured for use in a retrograde manner in **FIG. 3**, one embodiment of the anastomotic applier instrument **10** in accordance with the invention may comprise an elongated tube assembly **500**, a driver assembly **300** secured onto the distal end of the tube assembly **500**, an optional positioner assembly **400** which may be used to bring the bladder wall and the pelvic floor tissues into close proximity or contact, and an actuator handle **100** for effecting opening of the positioner and driver assemblies and the driving and seating of anchors. In general, the instrument may be used for performing a vesico-urethral anastomosis after the prostate has been removed in a radical retropubic prostatectomy (see **FIGS. 1 and 2**). This connection is necessary to restore the patient's urinary functions after the prostatectomy.

[0188] **FIG. 4** shows an embodiment of an actuator handle **100** of the anastomotic instrument shown in **FIG. 3**. Handle **100** is operatively connected to the proximal end of the elongated tube assembly **500**, which transmits manipulating and actuating forces from the handle **100** to the positioner assembly **400** and driver assembly **300** at the distal end of the tube assembly **500**. Two tubes, outer tube **510** and medial actuator tube **280**, exit handle **100** at its distal end. Outer tube **510** is affixed by any suitable means to and is substantially integral with handle housing **112**, and housing **112** and outer tube **510** are substantially stationary and skeletal with respect to the other, moving, parts of the handle **100** and tube assembly **500**. Medial actuator tube **280** both rotates and moves longitudinally with respect to outer tube **510**, in response to input from the surgeon as will be hereinafter described, and thereby transmits rotational and longitudinal actuating forces and movement through tube assembly **500**.

[0189] the embodiment shown in **FIGS. 4-6**, the handle **100** may comprise a housing **112** having actuating mechanisms disposed therein as will be hereinafter described. The housing **112** may include two or more parts, having alignment pins **105** and mating holes to facilitate assembly and make the parts integral after assembly.

[0190] Housing **112** contains actuating mechanisms to effect rotational and longitudinal actuating forces and movement in medial actuator tube **280**. Referring to **FIG. 5**, knob **110** may be an actuating member for manipulation by a surgeon, and may be adapted to be pushed distally by the surgeon, and urged back proximally by knob return spring **150**, with respect to housing **112**. Knob **110** may also be adapted to be rotated by the surgeon with respect to housing **112** by the surgeon. Thus, knob **110** may be rotatable and movable longitudinally within housing **112**, within the limits of longitudinal travel defined by knob track **116** in housing **112**, as the ends thereof stop longitudinal movement of knob **110** by contact with knob rim **111**. Knob **110** may also be hollow, having guidewire passage **114** therethrough. Within guidewire passage **114** of knob **110** may be one or more longitudinal spline grooves **115**. Spline grooves **115** can slidably mate with one or more splines **185** of proximal rotation tube **180**. Thus, it can be appreciated that knob **110** and proximal rotation tube **180** may be coupled with respect to rotational movement, but not coupled with respect to longitudinal movement and therefore, be longitudinally slidable with respect to one another. Thus configured, rotation of knob **110** can effect corresponding rotation of proximal rotation tube **180**. In turn, proximal rotation tube **180** may be fixedly coupled to medial actuator tube **280**. Thus, rotation of knob **110** can effect corresponding rotation of medial actuator tube **280**, while longitudinal movement of knob **110** will not effect longitudinal movement of medial actuator tube **280**.

[0191] Prior to the firing of the handle assembly as will be described below, knob **110** may be turned to effect corresponding rotational movement in medial actuator tube **280**, so as to open driver assembly **300** and positioner assembly **400** as will be described below.

[0192] **FIGS. 5 and 6**, depict handle **100** in an uncocked, pre-deployment position. As will be hereinafter described, one embodiment of an anchor driver assembly of the present invention (such as that shown in **FIG. 3** at **300**) requires longitudinal force and movement of a member in a proximal direction in order to drive anchors. This force and movement in a proximal direction may be effected by handle **100** via medial actuator tube **280**. Medial actuator tube **280** may be drawn in a longitudinally proximal direction, i.e., rearwardly, into handle **100**, through a mechanism that will now be described.

[0193] A driving spring **160** may be contained within housing **112**, in compression, as shown in **FIGS. 5 and 6**. The proximal end of driving spring **160** contacts and acts against the distal end of a proximal linking tube **140**, urging linking tube **140** to move in a proximal direction with respect to housing **112**. The proximal end of linking tube **140** rotatably and slidably fits around an interior spindle **117** of knob **110** and rests against spindle shoulder **118**.

[0194] In the position shown in **FIGS. 5 and 6**, driving tube **120** is in a forward, distal position inside housing **112**. Driving tube **120** is connected at its distal end to proximal rotation tube **180** via lip **123**, such that proximal rotation tube **180** is free to rotate within driving tube **120**, but by the arrangement shown, driving tube **120** and proximal rotation tube **180** are configured to be linked and move as a unit in a longitudinal direction. Driving tube **120** may be prevented from rotating so as not to interfere with actuation of driving button pawl **205**, by one or more pins **128** affixed in housing **112**, engaged in driving tube pin slot **129**. At the top of **FIG. 6**, it can be seen that driving button **202** may be integral with driving button pawl **205**, and driving button **202** and correspondingly driving button pawl **205** are biased in a counterclockwise direction by spring **235**, such that pawl **205** is biased downward into driving tube firing slot **210**.

[0195] In order the ready the handle depicted in **FIGS. 5 and 6** to effect a longitudinal proximal movement of medial actuator tube **280** (which movement may be used to drive anchors as will be hereinafter described), a surgeon may depress knob **110** in a longitudinal, distal direction within housing **112** (to the right with respect to **FIG. 5**). As a result of contact between shoulder **118** and the proximal end of linking tube **140**, this movement of knob **112** can move linking tube **140** a corresponding direction and distance, and also correspondingly, longitudinally compress and thereby charge driving spring **160**. Linking tube **140** has affixed at its proximal end one or more driving tube engagers **170**, which

may be spring-biased inwardly and have latching ends **171** that protrude inwardly through slots in linking tube **140** as shown. Upon longitudinal movement of linking tube **140** in a distal direction as a result of depressing knob **10**, latching ends **171** can moveably engage and latch upon latching shoulder **126** of driving tube **120**, latching driving tube **120** to linking tube **140** such that the two will move as a unit in a rearward, proximal longitudinal direction, in response to force exerted on linking tube **140** by driving spring **160**, once driving tube **120** is released as will be described below. Thus, when a surgeon depresses knob **110** in a distal longitudinal direction (to the right with respect to **FIG. 5**, driving spring **160** is charged and the handle is thereby cocked for driving anchors as will be hereinafter described. After cocking, knob **110** is urged to return to its proximal (rearward) position by knob return spring **150**. Knob return spring **150** and driving spring **160** may be coaxially aligned and separated by a spring divider **130**.

[**0196**] Driving tube **120** is released and permitted to be driven in a longitudinal proximal (rearward) direction with respect to housing **112** when the surgeon engages and urges driving button **202** forwardly (with respect to **FIG. 6**). This rotates driving button **202** and correspondingly, pawl **205** clockwise about pin **230**, and lifts pawl **205** out of driving tube firing slot **210**. Driving tube **120** is thereby released to be driven rearwardly (to the left with respect to **FIGS. 5 and 6**) under the force exerted by driving spring **160**, acting on linking tube **140**, linked to driving tube **120** via driving tube engagers **170**. As driving tube **120** is driven rearwardly, it correspondingly pulls medial actuator tube **280** rearwardly a corresponding distance, via lip **123**. This actuation constitutes "firing" the handle **100** to pull medial actuator tube **280** in a longitudinal proximal (rearward) direction into handle **100**, which may be used to drive anchors as will be described below.

[**0197**] After "firing" of handle **100**, it may be desirable to effect additional longitudinal movement of medial actuator tube **280** so as to cause further seating of anchors, and afterward, to effect withdrawal of anchor driver pins from anchors as will be described below. Referring to **FIG. 6**, after firing, driving tube retraction slot **225** in driving tube **120** is moved to a position beneath driving button pawl **205**, and pawl **205**, at the urging of torsion spring **235** and/or pressure by the surgeon, moves into retraction slot **225**. The surgeon may then exert proximal and downward pressure (with respect to **FIG. 6**) on driving button **202**, which will both maintain pawl **205** in retraction slot **225**, and also urge pin **230** down and out of rocker detent **238** in driving button slot **240**, enabling the surgeon to urge driving tube **120** further proximally and thus further drive anchors a distance allowed by seating extension **220** in driving button slot **240**, and/or further seat anchors into tissues, as will be described below. This arrangement may also transfer to the surgeon touch-perceptible feedback through driving button **202** as to how much pressure is being exerted to drive and seat anchors.

[**0198**] After driving and seating of anchors, the surgeon may then effect the withdrawal of anchor driver pins from anchors (as will be described below) by effecting a return of medial actuator tube to its original position as will now be described. The surgeon exerts downward and distally-directed pressure on driving button **202**. Such downward pressure maintains pawl **205** in retraction slot **225** and keeps pin **230** out of rocker detent **238**, while urging driving tube **120** distally (to the right with respect to **FIG. 6**). As driving tube **120** is urged distally, medial actuator tube **280** is urged distally a corresponding distance via driving tube lip **123** acting on proximal actuator tube **180**, which is affixed to medial actuator tube **280**. This returning motion is limited by the distal extent of driving button slot **240**. When pin **230** reaches this extent, the surgeon's release of pressure on driving button **202** will permit pin **230** to be urged upwardly (with respect to **FIG. 6**) under the force exerted by torsion spring **235** into extension detent **245**.

[**0199**] Following installation of anchors, knob **110** may be turned to effect corresponding rotational movement in medial actuator tube **280** so as to retract or close driver assembly **300** and positioner assembly **400** as will be described below.

[**0200**] It is contemplated that various pieces of the handle assembly may be an integral structure formed from several components, or these features may be an integrally molded from a material such as plastic so as to form a single integral structure. The handle assembly may be constructed from conventional materials for surgical instruments, for example a metal such as stainless steel or plastic. The instrument may be constructed primarily from conventional metal or plastic materials so that it is inexpensive to manufacture and can be disposable. The instrument may also be sold in a package that is presterilized for surgical use.

[**0201**] Housing **112**, driving button **202**, spring divider **130** and knob **110** may be formed of plastic or any suitable material having necessary properties of strength, stiffness and formability. It may be desirable for spline grooves **115** to be a suitable metal for improved hardness and wear resistance, such that spline grooves **115** would be part of a metal insert around which knob **110** is formed. Proximal actuator tube **180**, linking tube **140** and driving tube engagers **170**, driving tube **120**, medial actuator tube **280** and outer tube **510** may be formed of stainless steel, plastic or any other suitable material having necessary properties of strength, hardness and stiffness. Springs **150**, **160** and **235** may be formed of spring steel or any suitable material that would have suitable formability, shape memory, stiffness (spring constant) and strength properties. While proximal actuator tube **180**, linking tube **140**, driving tube **120**, medial actuator tube **280** and outer tube **510** are depicted as having tube shapes, they may also have any shape suitable for transmitting longitudinal and rotational forces and movement to a distal end as required for an instrument of the present invention.

[**0202**] It will be apparent to persons skilled in the art that a variety of mechanisms might be configured and adapted to transmit longitudinal (advancement and retraction) and rotational forces and movement move from a proximal handle assembly to a distal end in order to effect the forces and movement necessary to actuate an instrument of the present invention. It will be apparent to persons skilled in the art that the mechanism that supplies the driving force supplied by driving spring **160** may also be other biasing or driving devices including but not limited to levers, gears, pressurized gases/fluids and any other mechanisms for selectively deploying linear driving forces known in the art.

[**0203**] An alternative embodiment for the driving button assembly shown in **FIG. 6** will now be described. Referring

to **FIGS. 52-54**, driving button **202** is linked to the mechanism by driving button pin **230**, captured by driving button pin boss **206**. Driving button **202** includes driving button pawl **205**, driving pin boss **206**, driving trigger **204** and retraction member **207**. Driving button **202** is angularly movable about driving button pin **230** which is captured by driving pin boss **206**, and driving button pin **230** may slidably ride in a longitudinal direction with respect to the length of the instrument, in driving button groove **240**, which includes rocker detent **238**. One or more springs **235** are provided which act upon driving button **202** in two ways: First, to urge driving button **202** upward such that driving button pin **230** is urged upward, in orientation with respect to **FIGS. 52-54**, and such that driving pin **230** is urged into rocker detent **238**, when driving trigger **204** is not being depressed; second, to urge driving button **202** in a counterclockwise direction, such that driving trigger **204** and driving button pawl **205** are urged in a counterclockwise direction, about driving button pin **230**, with respect to **FIGS. 52-54**, thus maintaining driving button pawl **205** engaged with driving tube retention slot **210**. It will be appreciated that a single torsion spring configured and acting upon driving button **202** in a manner such as shown in **FIG. 6** (torsion spring **235**) may be used to accomplish the desired result, but also, that other suitable spring or biasing mechanisms or configurations are possible. Driving button pawl **205** is adapted to engage, alternatively, driving tube retention slot **210**, and driving tube retraction slot **225**, of driving tube **120**, in a manner similar to that shown for the driving button pawl **205** in **FIG. 6**.

[**0204**] Operation of the embodiment of driving button assembly shown in **FIGS. 52-54** will now be described. When an instrument such as driver assembly **300** (**FIG. 3**) has been loaded with anchors and is in the retracted position ready for insertion and subsequent use, driving button assembly **200** will be in the position shown in **FIG. 52**. Driving button **202** is biased upwardly and in a counterclockwise direction about driving button pin **230** by one or more springs **235** so that driving button pin **230** is maintained engaged in rocker detent **238**, and driving button pawl **205** is maintained engaged in driving tube retention slot **210**, restraining driving tube **120** against spring bias acting upon driving tube **120** as more fully described above.

[**0205**] Once the applier has been inserted and opened to the position shown in **FIG. 14**, the driving tube **120** is released and driven by depressing driving trigger **204**.

[**0206**] **FIG. 53** depicts a "snapshot" of the positioning of driving button **202** relative to driving tube **120**, after driving trigger **204** is depressed to release driving tube **120** by disengaging driving button pawl from driving tube retention slot. With respect to **FIG. 53**, it can be seen that downward pressure on driving trigger **204** causes clockwise rotation of driving button **202** about driving button pin **230**, causing driving button pawl **205** to move upwardly and disengage from driving tube retention slot **210**. Disengagement of driving button pawl **205** from driving tube retention slot **210** releases driving tube **120**, permitting it to move to the left (with respect to **FIGS. 52-54**) under urging of a spring as more fully described above. This drives driver pins and anchors as more fully described below.

[**0207**] **FIG. 54** illustrates the positioning of driving button **202** relative to driving tube **120**, when the mechanism is ready for retraction of the driver pins from the installed anchors. It will be appreciated from **FIGS. 53 and 54** that continuing downward pressure exerted by the surgeon on driving trigger **204** urges driving button pawl **205** downward into driving tube retraction slot **225**. At the same time, driving button pin boss **206** is urged downward, and correspondingly, driving button pin **230** is urged downward and out of rocker detent **238**. When driving button **202** is in this position, shown in **FIG. 54**, the surgeon may then engage retraction member **207** to move driving button **202** to the right (with respect to **FIG. 54**), which correspondingly pulls driving tube **120** to the right by engagement of driving button pawl **205** with driving tube retraction slot **225**. In this manner, the driver pins may be withdrawn from the now-installed anchors as more fully described below.

[**0208**] Referring back to **FIGS. 3 and 7-9**, it may be desirable that tube assembly **500** be curved and flexible to facilitate insertion into the patient. Accordingly, it may be desirable to manufacture certain components of tube assembly **500**, including outer tube **510**, medial actuator tube **280**, distal rotation tube **580** and central tube **590**, of materials that have suitable combined properties of biocompatibility, strength, stiffness, flexibility, elasticity and shape memory so as to provide a suitable balance of flexibility to facilitate insertion, with strength, rigidity and shape memory to facilitate manipulation to transfer longitudinal and rotational forces from the handle assembly **100** to the positioner assembly **400** and driver assembly **300**. The inventors have found that suitably treated nitinol, known in the art for having such properties and used for endoscopic surgical instruments with similar requirements, is a suitable material. However, other materials such as styrene or other polymers may be satisfactory for some components.

[**0209**] **FIGS. 7-10** are views of the portion of tube assembly including a bridge assembly **600**. The tube assembly and bridge assembly provide for isolation and transmission of rotational and longitudinal advancement and retraction force and movement from medial actuator tube **280** to a positioner assembly **400** and driver assembly **300**. In one embodiment, medial actuator tube **280** may rotate, and longitudinally advance and retract within and with respect to outer tube **510**, and is operatively connected to a positioner assembly **400** and a driver assembly **300**, via a bridge assembly **600**. The bridge assembly **600** provides an operative connection of the medial actuator tube **280** so as to limit rotational movement, and transmit both limited rotational movement and longitudinal movement to distal rotation tube **580**, and is adapted to allow an effective amount of rotational and longitudinal travel. The bridge assembly **600** also provides an operative connection of the medial actuator tube **280** to central tube **590** so as to translate longitudinal movement to central tube **590**.

[**0210**] Referring to **FIGS. 9 and 10**, medial actuator tube **280** has therein one or more bridge slots **640**, and terminates within bridge assembly **600**. Bridge **610** has a hub **650** located within medial actuator tube **280**, and one or more vanes **620**, which protrude through bridge slots **640** in medial actuator tube **280**, and longitudinally ride within one or more longitudinal bridge tracks **670** cut or formed within a bridge guide **660**. Bridge guide **660** is affixed within, and therefore integral with, outer tube **510**. Thus, vanes **620** and

therefore bridge **610** may slide longitudinally within bridge guide **660** and outer tube **510**, but are prevented from rotating.

[**0211**] It can be appreciated from **FIGS. 9 and 10** that the range of rotation of medial actuator tube **280** with respect to outer tube **510** is limited by the circumferential dimension of bridge slots **640** in medial actuator tube **280**, and contact between the edges of bridge slots **640** and vanes **620**. The circumferential dimension of bridge slots **640** in actuator tube **280** may be varied according to the range of rotation that may be required to actuate the instrument. Longitudinal bridge tracks **670** may be long enough to allow vanes **620** to slide longitudinally to the full range of longitudinal motion of medial rotation tube **280** that may be required to actuate the instrument.

[**0212**] Central tube **590** is affixed within bridge hub **650** and is integral therewith. Thus, longitudinal motion is translated from medial actuator tube **280** to bridge vanes **620** and correspondingly bridge hub **650** via interaction between bridge slots **640** and bridge vanes **620**. Correspondingly, longitudinal motion of bridge hub **650** is translated to central tube **590** because bridge hub **650** and central tube **590** are integral. Thus, longitudinal motion of medial actuator tube **280** is translated to corresponding longitudinal motion of central tube **590**.

[**0213**] At the same time, rotational motion of medial actuator tube **280** is not translated to central tube **590**. As noted, central tube **590** is integral with bridge hub **650**, and bridge hub **650** is prevented from rotating by the situation of bridge vanes **620** in bridge tracks **670**, which are, in turn, integral with outer tube **510**.

[**0214**] Referring to **FIG. 10**, distal rotation tube **580** is affixed and integral with rotation spacer **288**, which, in turn, is affixed and integral with the distal end of medial actuator tube **280**. Thus, both longitudinal movement and rotation of medial actuator tube **280** are translated directly to corresponding longitudinal movement and rotation of distal rotation tube **580**. As previously noted, however, the range of rotational movement of medial actuator tube **280** is limited by the circumferential dimension of bridge slots **640**, and thus, the range of rotational movement of distal rotation tube **580** is correspondingly limited.

[**0215**] Central tube **590** and distal rotation tube **580** are not affixed to one another and therefore distal rotation tube **580** may rotate with respect to central tube **590**.

[**0216**] A funnel guide **606** may be affixed to the proximal end **608** of central tube **590**, thereby providing for ease of feeding a guide wire upward through medial actuator tube **280** and into central tube **590**. Funnel guide **606** would not be affixed to medial actuator tube **280**, and would be longitudinally and rotationally movable therein.

[**0217**] Distal rotation tube **580** and central tube **590** may be located within and supported through a bend in the tube assembly by rotation tube stabilizer **530**, a proximal end of which appears at the right of **FIGS. 8 and 10**, and the entirety of which appears in **FIG. 7**.

[**0218**] Referring now to **FIG. 11-16**, the tube assembly is operably coupled with positioner assembly **400**. A proximal positioner mount **410** is affixed and integral with outer tube **510**. Distal positioner mount **440** is affixed and made integral with proximal positioner mount **410** by positioner mount connector members **412**. Thus, proximal positioner mount **410** and distal positioner mount **440**, as made integral with outer tube **510**, provide a stationary reference and mounting point for moving parts which will now be described.

[**0219**] Referring to **FIGS. 11 and 12**, as noted and described above, central tube **590** may move longitudinally, but may not rotate, with respect to outer tube **510**, and thus, may move longitudinally, but may not rotate, with respect to proximal positioner mount **410** and distal positioner mount **440**. Central tube **590** is affixed and integral at its distal end with distal end cap **390**. Distal driver mount **340** is affixed and integral with tabs **392** of distal end cap **390**. Proximal driver mount **310** is affixed and made integral with distal driver mount **340** via driver mount connector members **314**. Thus, distal end cap **390**, distal positioner mount **340**, driver mount connector members **314** and proximal driver mount **310** and central tube **590** are integral and move longitudinally as a unit with respect to outer tube **510**, but may not rotate with respect to outer tube **510**.

[**0220**] It can be seen from **FIGS. 3-14** that guidewire passage **114** leads through the center of handle assembly **100**, through tube assembly **500** (and within medial actuator tube **280**), through central tube **590**, through positioner assembly **400** and driver assembly **300** and out distal end cap **390**.

[**0221**] As noted and described above, distal rotation tube **580** may rotate about central tube **590**, in direct correspondence with rotation of medial actuator tube **280**, within a range limited by the circumferential dimension of bridge slots **640** in medial actuator tube **280** (see **FIGS. 9 and 10**). Within driver assembly **300**, distal rotation tube **580** terminates and is integrally affixed to distal rotation tube collar **394** and gear tube **380**. Thus, rotation of distal rotation tube **580** causes directly corresponding rotation of gear tube **380**. In **FIGS. 11 and 12**, it can be seen that gear tube **380** resides directly outside distal rotation tube **580** and extends proximally from distal driver mount **340** to proximal positioner mount **410**. In **FIG. 11**, it can be seen that clearance within rotation tube stabilizer **530** is present to permit proximal longitudinal movement of gear tube **380** thereinto.

[**0222**] Referring again to **FIG. 12**, and also **FIG. 14**, it can be seen that distal driver gear **360** and proximal driver gear **320** reside within driver assembly **300**. Distal driver gear **360** and proximal driver gear **320** are coaxial and integrally affixed to gear tube **380**. Arcuate slots **361** in distal driver gear **360** and arcuate slots **321** in proximal driver gear **320** accommodate passage of driver mount connector members **314** therethrough and also permit distal driver gear **360** and proximal driver gear **320** to rotate within a limit about the axis of gear tube **380** without interference from driver mount connector members **314**.

[**0223**] Referring to **FIG. 11**, distal positioner gear **460** and proximal positioner gear **420** reside within positioner assembly **400**. Distal positioner gear **460** and proximal positioner gear **420** are coaxial with, and longitudinally splined with, gear tube **380**, such that distal positioner gear **460** and proximal positioner gear **420** are coupled with gear tube **380** with respect to rotation, but uncoupled with respect to relative longitudinal motion. Thus, gear tube **380** may move longitudinally within positioner assembly **400**, without

effecting corresponding longitudinal movement of positioner assembly **400** or any parts thereof. Arcuate slots **461** in distal driver gear **460** and arcuate slots **421** in proximal driver gear **420** accommodate passage of driver mount connector members **412** therethrough and also permit distal positioner gear **460** and proximal positioner gear **420** to rotate within a limit about the axis of gear tube **380** without interference from positioner mount connector members **412**.

[**0224**] Thus, it can be appreciated from the description above that rotating medial actuator tube **280** correspondingly rotates distal rotation tube **580** and gear tube **380**, and finally, distal driver gear **360**, proximal driver gear **320**, distal positioner gear **460** and proximal positioner gear **420**. It also may be seen that longitudinal movement of central tube **590** with respect to outer tube **510** causes corresponding longitudinal movement of driver assembly **300** with respect to outer tube **510**, but not longitudinal movement of positioner assembly **400** with respect to outer tube **510**.

[**0225**] Referring now to **FIGS. 11, 13** and **14**, distal positioner pinions **462** are integral with and may rotate about pinion shafts (not shown) which are rotatably supported in distal positioner mount **440**. Distal positioner pinions **462** mesh with distal positioner gear **460**, and may be driven thereby. Distal positioner pinions **462** are also integral with distal positioner arms **470**. Similarly, proximal positioner pinions **422** are integral with and may rotate about pinion shafts (not shown) which are rotatably supported in proximal positioner mount **410**. Proximal positioner pinions **422** mesh with proximal positioner gear **420**, and may be driven thereby. Proximal positioner pinions **422** are also integral with proximal positioner arms **430**.

[**0226**] Thus, referring to **FIGS. 11, 13** and **14**, it can be seen that rotation of distal rotation tube **580** correspondingly rotates gear tube **380**, and thus, distal and proximal positioner gears **460** and **420**, which, in turn, drive distal and proximal positioner pinions **462** and **422**, causing positioner arms **470** and **430** to either swing outwardly (toward a position shown in **FIG. 14**) or inwardly (toward a position shown in **FIG. 13**). It will be appreciated that the position shown in **FIG. 13** is the position in which positioner assembly **400** would be placed during insertion into and retraction from a patient. It will be further appreciated that the position shown in **FIG. 14** is the position in which positioner assembly **400** is ready for use for bringing the bladder wall surrounding the bladder opening into contact with the pelvic floor, as will be further described below. Finally, it will be appreciated from the description set forth above (and referring also to **FIGS. 8-10**), that the limits of the rotational motion of gear tube **380** required, alternately, to extend or retract arms **470** and **430** of positioner assembly **400**, are defined by the circumferential dimension of bridge slots **640** in medial rotation tube **280** and their interaction with bridge vanes **620**.

[**0227**] Referring now to **FIGS. 12-16**, distal driver pinions **362** are integral with pinion shafts **316**, which are rotatably supported in distal driver mount **340**. Distal driver pinions **362** mesh with distal driver gear **360**, and may be driven thereby. Distal driver pinions **362** are also integral with distal driver arms **370**, which, in turn, are integral with driver pins **376**. Similarly, proximal driver pinions **322** are integral with pinion shafts **316**, which are rotatably supported in proximal driver mount **310**. Proximal driver pinions **322** mesh with proximal driver gear **320**, and may be driven thereby. Proximal driver pinions **322** are also integral with proximal driver arms **330**, which, in turn, are integral with additional driver pins **376**.

[**0228**] Thus, referring to **FIGS. 12-16**, it can be seen that rotation of distal rotation tube **580** correspondingly rotates gear tube **380**, and thus, distal and proximal driver gears **360** and **320**, which, in turn, drive distal and proximal driver pinions **362** and **322**, causing driver arms **370** and **330** to either swing outwardly (toward a position shown in **FIG. 14**) or inwardly (toward a position shown in **FIG. 13**). It will be appreciated that the position shown in **FIG. 13** is the position in which driver assembly **300** would be placed during insertion into and retraction from a patient. It will be further appreciated that the position shown in **FIG. 14** is the position in which driver assembly **300** is ready for driving anchors, as will be further described below. Finally, from the description set forth above (and referring also to **FIGS. 8-10**), it will be appreciated that the limits of the rotational motion of gear tube **380** required, alternately, to extend or to retract arms **370** and **330** of driver assembly **300**, are defined by the circumferential dimension of bridge slots **640** in medial rotation tube **280** and their interaction with bridge vanes **620**.

[**0229**] Referring to **FIG. 14**, one or more driver pins **376** are affixed to driver arms **330** and **370**. Each of the one or more driver pins **376** are adapted to retain anchors **700** having anchor heads **710**, for example, by friction fit or other suitable means. Anchors **700** may have hollow bores within, opening at their heads **710**, and extending substantially within their lengths, and driver pins **376** may extend within such bores substantially the entire lengths thereof, so that the distal ends of driver pins **376** drive anchors **700** at their forward ends, so as to prevent anchors **700** from buckling or veering off-direction as they might otherwise do if driven at their rearward ends proximate to heads **710**.

[**0230**] Still referring to **FIGS. 10-14**, longitudinal force and movement may be translated to the driver arms **370** to, alternately, drive anchors **700** into tissues, and withdraw driver pins **376** from anchors **700** after they are installed into tissues, as follows. As previously noted and described, longitudinal force and movement is translated directly from medial actuator tube **280** to central tube **590** via bridge assembly **600**. As noted, central tube **590** is integral with distal end cap **390**, distal driver mount **340**, driver mount connector member **314** and proximal driver mount **310**. Because driver arms **330** and **370** are operably mounted within driver mounts **310** and **340**, longitudinal force and movement exerted via medial actuator tube **280**, translated to central tube **590**, is also translated directly to longitudinal force and movement of driver arms **330** and **370** (and entire driver assembly **300**), and thus to driver pins **376** and anchors **700**. As can be appreciated from the description above, gear tube **380** will be moved longitudinally in correspondence with longitudinal movement of central tube **590** and driver assembly **300**. As noted, gear tube **380** is permitted to longitudinally move relative to and through positioner assembly **400** by means of longitudinal splines coupling gear tube **380** with proximal and distal positioner gears **420** and **460**, without effecting corresponding longitudinal movement thereto.

[**0231**] It will be appreciated that sufficient proximal longitudinal movement should be provided and translated to

driver arms **330** and **370** and driver pins **376** by the mechanism described above so as to carry and drive anchors **700** past positioner assembly **400** and into the target tissues. The advancement/retraction longitudinal travel distance of the driver assembly **300** can be generally greater than the length of the anchors **700** in order to move the anchors past the positioner and fully seat the anchors into the target tissues. In the embodiment shown and described thus far, the position of the anchors when installed in the tissues may be substantially parallel with the longitudinal axis of the driver assembly **300**, but the position of the anchors may also be at an angle therewith. Additionally, in the embodiment shown and described thus far, the anchors may enter the target tissues substantially perpendicular with them, as they are held by positioner assembly **400**.

[**0232**] It is also contemplated that various integral components of the positioner and driver assemblies described above may be formed, molded or machined as a unitary, continuous structure. For example, driver arms **330** and **370** may be unitary and continuous with driver pins **376**, rather than be assembled pieces.

[**0233**] Referring now to **FIGS. 3 and 31-38**, a surgeon may use the embodiment just described in a retrograde direction in the following manner. The driver assembly **300** may be loaded with one or more anchors **700**, as may be required, prior to use. The instrument may then be inserted into the urethra and advanced in a retrograde direction until the distal end of the instrument **10** is through the urethra **5** (**FIG. 31**), through the bladder opening **4**, and the driver assembly **300** and positioner assembly **400** are inside the bladder lumen **8**.

[**0234**] After insertion into the bladder **1**, instrument **10** may be initially actuated by rotating knob **110** to open the positioner and driver assemblies to the initial deployment position as shown in **FIG. 32** (see also **FIG. 14**). The entire instrument may then be retracted by pulling handle **100** in a proximal direction downwardly through the urethra **5**, bringing the opened positioner assembly into contact with the bladder wall **2** surrounding the bladder opening **4**, and urging bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6**, with the respective openings **4** and **6** aligned, as shown in **FIG. 33**. Once in position, the instrument may then be prepared for further actuation by cocking the handle mechanism by depressing knob **110** as described above. Next, it may be further actuated to drive anchors **700** by depressing driving button **202**, which will actuate the mechanism in handle assembly **100** previously described so as to pull driver assembly **300** in a proximal direction with respect to positioner assembly **400**, driving anchors **700** into and through the bladder wall **2** and into the underlying pelvic floor **7**, in positions surrounding the aligned openings **4** and **6**, to positions shown in **FIG. 34**. As noted above, using driving button **202**, the surgeon may then desire to further actuate the handle assembly **100** to further seat anchors **700** into the tissues. Next, still using driving button **202** as described above, the surgeon may push driver assembly **300** in a distal direction, withdrawing driver pins **376** from the installed anchors **700**, to the position shown in **FIG. 35**. Finally, knob **110** may be rotated again to re-close driver assembly **300** and positioner assembly **400** to the position shown in **FIG. 36**. In the closed position, the instrument **10** can then be withdrawn back out of the urethra **5**. Optionally, prior to withdrawal of the instrument from the urethra, a guide wire **80** may be inserted through the instrument (via a guide wire passage) and into the bladder lumen, and left behind for use described below after withdrawal of the instrument, see **FIGS. 36 and 37**.

[**0235**] Referring to **FIG. 38**, guide wire **80** may then be used to guide a balloon catheter system **90** into the bladder lumen **8**. As shown in **FIG. 38**, one embodiment provides for a balloon catheter system **90** wherein a balloon **94** is expanded to hold the catheter in place. Drainage holes **92** allow urine to drain from the bladder **1** through a catheter tube **96** into a urine collection bag **98**.

[**0236**] In another embodiment of the present invention, referring to **FIGS. 3 and 4**, the actuator knob **110** is depressed first to cock the actuator. Then the actuator knob is rotated causing a concurrent rotation of the distal rotation tube, which thereby opens the positioner and driver arms, and the anchors, to a distance of approximately 2-8 mm out and parallel with the longitudinal axis of the driver assembly.

[**0237**] It can be appreciated by one skilled in the art that the positioner and driver assemblies may have alternate configurations providing an instrument adapted to for use in a retrograde manner as described above, or in an antegrade manner.

[**0238**] It can be appreciated by one skilled in the art that the positioner assembly may have a variety of alternative configurations including but not limited to embodiments described herein (and thus including, without limitation, shuttlecock assembly **800** with positioner petals **830** (**FIGS. 17-21**), umbrella assembly **900** with reverse positioner petals **930** (**FIGS. 22-27**), positioner assembly **1440** with positioner arms **1441** (**FIGS. 56-64**; **70**, **71**, **77**, **78**), or positioner **2017** (**FIGS. 122-126**), **2090** (**FIGS. 110-118**), **2122** (**FIGS. 95, 96, 103-109**) and **2168** (**FIGS. 83, 84, 89-94**) (all of which are described below)), providing an alternately retractable and transversely extendible device useful for, referring to **FIG. 2**, insertion in a retracted position in a retrograde direction through the urethra **5** and into bladder opening **4**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned; or alternatively, insertion in a retracted position in an antegrade direction through an incision in the abdomen and an upper surface of the bladder **1**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned. Generally, the positioner assembly may comprise and make use of any number of alternately extendable and retractable projections, petals, arms, claws, or other grasping or catching members for catching and gaining control of bladder wall **2** surrounding bladder opening **4**. The positioner assembly may have at least one member operably connected to a longitudinal member of the instrument and alternately transversely extendable from and retractable toward the longitudinal axis thereof in response to input by a surgeon at a proximal end of the instrument.

[**0239**] Alternatively, it can be appreciated by one skilled in the art that when an anchor driver assembly is included

with the instrument that is functional to open and subsequently drive anchors through the bladder wall and into the pelvic floor as described herein, the positioner assembly or positioner as shown may be dispensed with in some circumstances. For example, referring to **FIGS. 32 and 33**, it can be appreciated that driver assembly **300**, when opened and drawn downwardly until the distal ends of anchors **700** contact and possibly puncture bladder wall **2** surrounding bladder opening **4**, can be sufficient for use in capturing bladder wall **2** and drawing it downward into contact with, and securing it to, pelvic floor **7**, with bladder opening **4** and urethra opening **6** aligned, without the need for positioner assembly **400** as shown, in some circumstances. Thus, driver assembly **300** with anchors **700** may serve a dual function as a positioner and as an anchor driver assembly.

"Shuttlecock" Embodiment

[**0240**] **FIGS. 17-21** illustrate another embodiment of a method and apparatus of the invention. As shown in **FIGS. 17-19**, a "shuttlecock" assembly **800** is provided. (As used herein, the term "shuttlecock" is only used for convenient reference to the present embodiment described, because as depicted in the drawings it bears some resemblances to a shuttlecock. The term is not, however, intended to connote any limitations, concerning appearance or otherwise. Those skilled in the art will appreciate that an instrument incorporating the features and functions described may or may not bear resemblances to a shuttlecock.) Affixed at the distal end of central tube **590** is distal end cap **390**. Central tube **590** may be located within positioner petal retainer actuator tube **810**, and positioner petal retainer actuator tube **810** may be located within driver pin actuator tube **820**, and it can be appreciated from **FIGS. 17 and 18** that the three tubes **590**, **810** and **820** may be substantially coaxial. Tubes **590**, **810** and **820** can also be longitudinally movable with respect to each other.

[**0241**] Driver pins **376** may be affixed at one end to the distal end of driver pin actuator tube **820**. Driver pins **376** may be made of spring wire or other suitable material having shape memory, and may include shorter lengths affixed to the distal end of driver pin actuator tube **820**, bends **377**, and greater lengths which receive detachable hollow anchors **700**. Prior to use of the instrument, anchors **700** may be loaded onto driver pins **376**, and may be releasably held thereon by friction fit or any other suitable means. When assembly **800** is in the retracted position shown in **FIG. 17**, the greater lengths of driver pins **376** may be held in a retracted position lying substantially along tube **820** as shown. When assembly **800** is in the opened position shown in **FIG. 19**, the spring bias in bends **377** of driver pins **376** can cause the greater lengths and free ends of driver pins **376**, and correspondingly, anchors **700** on driver pins **376**, to move outwardly to the opened position shown. Anchors **700** may have hollow bores within, opening at their heads **710**, and extending substantially within their lengths, and driver pins **376** may extend within such bores substantially the entire lengths thereof, so that the distal ends of driver pins **376** may apply driving force proximate to the forward ends of anchors **700**, so as to prevent anchors **700** from buckling or veering off-direction as they might otherwise do if driven at their rearward ends proximate to heads **710**.

[**0242**] Each of positioner petals **830** may be affixed at one end to distal end cap **390**. Positioner petals **830** may be made of a spring metal or other suitable material having shape memory, biased so as to spring outwardly to the opened position shown in **FIG. 19** when unrestrained, or may simply ride passively on top of driver pins **376** and anchors **700**, being flexibly affixed or hinged to distal end cap **390**. When assembly **800** is in the retracted position shown in **FIG. 17**, positioner petals **830** lie in a retracted position as shown, to the outside of driver pins **376** and anchors **700**. When assembly **800** is in the opened position shown in **FIG. 19**, the tips **835** of positioner petals **830** have been moved outwardly to an opened position shown, wherein the angle formed by the lengths of positioner petals **830** and the axis of tubes **590**, **810** and **820** may be approximately **15** degrees.

[**0243**] When assembly **800** is in the retracted position shown in **FIG. 17**, positioner petals **830**, and driver pins **376** and anchors **700**, may be retained against the urging of the spring bias in driver pins **376**, by positioner petal retainer **860**. As shown in **FIG. 18**, positioner petal retainer **860** is connected to and made integral with positioner petal retainer actuator tube **810** by positioner petal retainer braces **862**. As noted above, positioner petal retainer actuator tube **810** is longitudinally movable with respect to central tube **590** and driver pin actuator tube **820**.

[**0244**] As shown in **FIG. 19**, driver pins **376** and positioner petals **830** are allowed to move to their opened positions when positioner petal retainer **860** is moved upwardly toward distal end cap **390** (see also **FIG. 29**). Because positioner petal retainer **860** is integral with positioner petal retainer actuator tube **810** via positioner petal retainer braces **862**, pushing positioner petal retainer actuator tube **810** toward distal end cap **390**, while holding central tube **590** and driver pin actuator tube **820** stationary, moves positioner petal retainer **860** toward distal end cap **390**, releasing and allowing positioner petals **830** and driver pins **376** and anchors **700** to open to the position shown in **FIG. 19** (see also **FIGS. 28, 29**). It can be understood from **FIG. 18** that the positioning of positioner petal retainer braces **862** between the separate positioner petals **830** permits this relative motion.

[**0245**] As may be seen in **FIG. 17**, the entire shuttlecock assembly **800**, including the central tube **590**, positioner petal retainer actuator tube **810** and driver pin actuator tube **820**, are carried by the outer tube **510** and centered therein by the outer tube end collar **805**. It will be understood by those skilled in the art that tubes **590**, **810**, **820** and **510** may be held stationary and/or selectively longitudinally moved with respect to each other by any suitable proximal actuating mechanism.

[**0246**] Use and operation of this embodiment to perform anastomosis in a retrograde manner to join a patient's bladder and urethra following radical prostatectomy will now be described. Referring to **FIG. 2** for anatomical reference, shuttlecock assembly **800** (in a retracted position such as shown in **FIG. 17**) is inserted into the patient's urethra, and guided up through the urethra **5**, through bladder opening **4**, and into the bladder lumen **8**, to a fully inserted position whereby shuttlecock assembly **800** may be opened within the bladder as will be hereinafter described.

[**0247**] Once assembly **800** is in the fully inserted position, referring back to **FIGS. 17 and 19**, positioner petals **830** and driver pins **376** with anchors **700** are opened by pushing positioner petal retainer actuator tube **810** toward distal end

cap **390** while holding central tube **590** and driver pin actuator tube **820** stationary. Positioner petal retainer **860**, being integral with positioner petal retainer actuator tube **810** via positioner petal retainer braces **862**, is thus moved toward distal end cap **390**, which in turn allows positioner petals **830** and driver pins **376** with anchors **700** to spring outwardly into the opened position as shown in **FIG. 19**.

[**0248**] Again referring to **FIG. 2** for anatomical reference, the entire assembly **800**, now in the opened position within the patient's bladder, is then pulled toward the urethra opening **6** by withdrawing tubes **590**, **810**, **820** and **510**, together, back down through the urethra. This brings positioner petal tips **835** into contact with the inside of the bladder wall **2** at positions about bladder opening **4**, and urges bladder wall **2** surrounding bladder opening **4** toward pelvic floor **7** surrounding urethra opening **6**, bringing these tissues into contact with openings **4** and **6** aligned.

[**0249**] Once the bladder wall **2** and pelvic floor **7** are brought into contact, the next step is to drive anchors **700**, by retracting driver pin actuator tube **820** while holding the remaining tubes **590** and **810** stationary. Retracting driver pin actuator tube **820** causes affixed driver pins **376** to drive anchors **700** into and through bladder wall **2**, as shown in **FIG. 20**, and then into pelvic floor **7**, as shown in **FIG. 21**. It will be appreciated that barbs **730** on anchors **700** cause anchors **700** to lodge in pelvic floor **7**, and that heads **710** on anchors **700** act to retain bladder wall **2** in a position in contact with pelvic floor **7**, such that bladder opening **4** is held in communication with urethra opening **6**.

[**0250**] As with the first embodiment described herein, optionally, prior to withdrawal of the instrument from the urethra, a guide wire may be inserted through the instrument (via a guide wire passage) and into the bladder lumen, and left behind for use described above after withdrawal of the instrument, see **FIGS. 37 and 38**.

[**0251**] The sequence of steps described above is then reversed to enable withdrawal of the shuttlecock instrument **800** from the patient. Driver pin actuator tube **820** is pushed while holding remaining tubes **590** and **810** stationary, causing driver pins **376** to withdraw from anchors **700**, which are now lodged in pelvic floor **7** through bladder wall **2**. The entire assembly **800**, still in the opened position inside bladder lumen **8**, is then pushed slightly further into the bladder lumen and away from the urethra by pushing tubes **590**, **810**, **820** and **510**, together, back upwardly. The instrument **800** is then brought into a closed position by retracting positioner petal retainer actuator tube **810** while holding central tube **590** and driver pin actuator tube **820** stationary. Positioner petal retainer **860**, being integral with positioner petal retainer actuator tube **810** via positioner petal retainer braces **862**, is thus moved in a proximal direction to a position away from distal end cap **390**, which in turn urges positioner petals **830** and driver pins **376** inwardly into the retracted position (but now without anchors **700**) as shown in **FIG. 17**. In a retracted position, the entire assembly **800** may then be withdrawn downwardly through the urethra and out of the patient.

[**0252**] It can be appreciated by one skilled in the art that the shuttlecock assembly described above may be in alternate configurations providing an instrument adapted for use in a retrograde manner as described above, or an antegrade manner.

[**0253**] It can be appreciated by one skilled in the art that the mechanism comprising the positioner petals and performing the bladder positioning function thereof may have a variety of alternative configurations including but not limited to embodiments described herein (and thus including, without limitation, the positioner assembly **400** described above (FIGS. **11**, **13-14**), umbrella assembly **900** with reverse positioner petals **930** (**FIGS. 22-27**), positioner assembly **1440** with positioner arms **1441** (**FIGS. 56-64**; **70**, **71**, **77**, **78**), or positioner **2017** (**FIGS. 122-126**), **2090** (**FIGS. 110-118**), **2122** (**FIGS. 95**, **96**, **103-109**) and **2168** (**FIGS. 83**, **84**, **89-94**) (all of which are described below), providing a transversely retractable and extendible device useful for, referring to **FIG. 2**, insertion in a retracted position in a retrograde direction through the urethra **5** and into bladder opening **4**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned; or alternatively, insertion in a retracted position in an antegrade direction through an incision in the abdomen and an upper surface of the bladder **1**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned. Generally, the positioner assembly may comprise and make use of any number of alternately extendable and retractable projections, petals, arms, claws, or other grasping or catching members for catching and gaining control of bladder wall **2** surrounding bladder opening **4**. The positioner assembly may have at least one member operably connected to a longitudinal member of the instrument and alternately transversely extendable from and retractable toward the longitudinal axis thereof in response to input by a surgeon at a proximal end of the instrument.

[**0254**] Alternatively, it can be appreciated by one skilled in the art that when an anchor driver assembly is included with the instrument, that is functional to open and subsequently drive anchors through the bladder wall and into the pelvic floor as described herein, the positioner assembly or positioner petals as shown may be dispensed with in some circumstances. For example, referring to **FIGS. 20 and 21**, it can be appreciated that anchor driver pins **376** and anchors **700**, when opened within the bladder lumen and drawn downwardly until the distal ends of anchors **700** contact and possibly puncture bladder wall **2** surrounding bladder opening **4**, can be sufficient for use in capturing bladder wall **2** and drawing it downward into contact with, and securing it to, pelvic floor **7**, with bladder opening **4** and urethra opening **6** aligned, without the need for positioner petals **830** as shown, in some circumstances. Thus, driver pins **376** with anchors **700** may serve a dual function as a positioner and as an anchor driver assembly.

"Umbrella" Embodiment

[**0255**] **FIGS. 22-27** illustrate another embodiment of the method and apparatus of the invention. As shown in **FIGS. 22-25**, an "umbrella" assembly **900** is provided. (As used herein, the term "umbrella" is only used for convenient reference to the present embodiment described, because as depicted in the drawings it bears some resemblances to an umbrella. The term "umbrella" is not, however, intended to

connote any limitations, concerning appearance or otherwise. Those skilled in the art will appreciate that an instrument incorporating the features and functions described may or may not bear resemblances to an umbrella.) Affixed at the distal end of central tube **590** is distal end cap **390**, and central tube **590** and distal end cap **390** are integral. Central tube **590** may be located within driver pin spreader tube **893**, and driver pin spreader tube **893** is located within reverse positioner petal tube **935**, and it can be appreciated from **FIG. 22** that the three tubes **590**, **893** and **935** may be substantially coaxial. Tubes **590**, **893** and **935** can be also longitudinally movable with respect to each other.

[**0256**] Driver pins **376** having bases **395** are affixed to end cap **390**. Driver pins **376** may be made of spring wire or other suitable material having shape memory, and include lengths and free ends that receive detachable hollow anchors **700**. Prior to use of the instrument, hollow anchors **700** may be loaded onto driver pins **376**, and releasably held thereon by friction fit or any other suitable means. When assembly **900** is in the retracted position shown in **FIG. 22**, the greater lengths of driver pins **376** may be held in a retracted position substantially parallel with the axis of tubes **590**, **893** and **935**, by spring bias or shape memory in driver pins **376**. When assembly **900** is in the fully opened position shown in **FIG. 25**, the lengths and free ends of driver pins **376** have been urged outwardly to an opened position as shown. Anchors **700** may have hollow bores within, opening at their heads **710**, and extending substantially within their lengths, and driver pins **376** may extend within such bores substantially the entire lengths thereof, so that the distal ends of driver pins **376** may apply driving force proximate to the forward ends of anchors **700**, so as to prevent anchors **700** from buckling or veering off-direction as they might otherwise do if driven at their rearward ends proximate to heads **710**.

[**0257**] As may be appreciated by comparing **FIGS. 24 and 25**, driver pins **376** with anchors **700** are moved from the retracted position to the opened position by movement of driver pin spreader **890** toward distal end cap **390**. Driver pin spreader is hollow and integral with driver pin spreader tube **893**, and may move longitudinally with respect to central tube **590** and reverse positioner petal tube **935**. Thus, as driver pin spreader tube **893** is moved toward distal end cap **390**, angled upper spreader face **891** of driver pin spreader **890** urges anchors **700** and correspondingly, driver pins **376**, radially outwardly to the opened position shown in **FIG. 25**.

[**0258**] As may be seen in **FIGS. 23 and 24**, reverse positioner petals **930** are integral with reverse positioner petal tube **935**. Reverse positioner petals **930** are made of spring metal or other suitable material having shape memory, and are biased to assume the opened position shown in **FIG. 24**. Thus, pushing reverse positioner petal tube **935** toward distal end cap **390** while holding the other tubes **590**, **893** and **510** stationary pushes positioner petals **930** out of outer tube **510** through outer tube end collar **805** and allows them to open to their biased positions shown in **FIGS. 24 and 25**.

[**0259**] As may be seen in **FIG. 22**, the entire umbrella assembly **900**, including the central tube **590**, driver pin spreader tube **893** and reverse positioner petal tube **935**, are carried by the outer tube **510** and centered therein by the outer tube end collar **805**. It will be understood by those skilled in the mechanical design arts that tubes **590**, **893**, **935** and **510** may be held stationary or selectively longitudinally moved with respect to each other by any suitable proximal actuating mechanism.

[**0260**] Use and operation of this embodiment to perform anastomosis to join a patient's bladder and urethra following radical retropubic prostatectomy will now be described. Referring to **FIG. 2** for anatomical reference, umbrella assembly **900** (in retracted position as shown in **FIG. 22**) is inserted into the patient's urethra, and guided up through the urethra **5**, and into bladder lumen **8** through bladder opening **4**, to a fully inserted position whereby umbrella assembly **900** may be opened within the bladder lumen as will be hereinafter described.

[**0261**] Once assembly **900** is in the fully inserted position, referring back to **FIGS. 22 and 24**, reverse positioner petals **930** are extended and opened by pushing reverse positioner petal tube **935** toward distal end cap **390** while holding central tube **590** and driver pin spreader tube **893** stationary. Next, referring to **FIGS. 24 and 25**, driver pins **376** with anchors **700** are opened by pushing driver pin spreader tube **893** toward distal end cap **390** while holding central tube **590** and reverse positioner petal tube **935** stationary. Thus assembly **900** is brought into the fully opened position shown in **FIG. 25**.

[**0262**] Again referring to **FIG. 2** for anatomical reference, the entire assembly **900**, now in the fully opened position within bladder lumen **8**, is then pulled toward urethra opening **6** by withdrawing all tubes **590**, **893**, **935** and **510**, together, back down through the urethra. This brings reverse positioner petals **930** into contact with bladder wall **2** at positions about bladder opening **4**, and urges bladder wall **2** toward and into contact with pelvic floor **7** about urethra opening **6**, with the respective openings **4** and **6** aligned.

[**0263**] Once the bladder wall and pelvic floor are brought into contact, the next step is to drive anchors **700**, by pulling central tube **590** while holding the remaining tubes **893** and **935** stationary. Pulling central tube **590** causes driver pins **376** to drive anchors **700** into and through bladder wall **20**, and then into pelvic floor **7**, as shown in **FIG. 26**. It will be appreciated that barbs **730** on anchors **700** cause anchors **700** to lodge in pelvic floor **7**, and that heads **710** on anchors **700** act to retain bladder wall **20** in a position in contact with pelvic floor **7**, such that bladder opening **4** is held in communication with urethra opening **6**.

[**0264**] As with the first embodiment described herein, optionally, prior to withdrawal of the instrument from the urethra, a guide wire may be inserted through the instrument (via a guide wire passage) and into the bladder lumen, and left behind for use described above after withdrawal of the instrument, see **FIGS. 37 and 38**.

[**0265**] The sequence of steps described above is then reversed to enable withdrawal of the umbrella instrument **900** from the patient. Central tube **590** is pushed while holding the remaining tubes **893** and **935** stationary, causing driver pins **376** to withdraw from anchors **700**, which are now lodged in pelvic floor **7** through bladder wall **2**. The entire assembly **900**, still in the opened position inside the patient's bladder, is then pushed slightly further into the bladder and away from the urethra by pushing tubes **590**, **893**, **935** and **510**, together, back into the urethra. The

instrument **900** is then brought into the retracted position as follows: Pulling driver pin spreader tube **893** while holding central tube **590** and reverse positioner petal tube **935** stationary moves driver pin spreader **890** from the position shown in **FIG. 25** to the position shown in **FIG. 24**, allowing driver pins **376** to return to their normally biased, retracted positions shown in **FIG. 24** (but now without anchors **700**). Next, pulling reverse petal tube **935** while holding central tube **590** and driver pin spreader tube **893** stationary withdraws reverse positioner petals **930** from their normally biased, opened positions shown in **FIG. 24**, to their retracted positions inside outer tube **510**, shown in **FIG. 22**. In the retracted position shown in **FIG. 22**, the assembly **900** may then be withdrawn downwardly through the urethra and out of the patient.

[**0266**] It can be appreciated by one skilled in the art that the positioner assembly may be in alternate configurations providing an applier adapted to for use in a retrograde manner as describe above, or an antegrade manner.

[**0267**] It can be appreciated by one skilled in the art that the mechanism comprising the positioner petals and performing the bladder positioning function thereof may have a variety of alternative configurations including but not limited to embodiments described herein (and thus including, without limitation, the positioner assembly **400** (**FIGS. 11, 13, 14**) or shuttlecock assembly **800** with positioner petals **830** (**FIGS. 17-21**) described above, positioner assembly **1440** with positioner arms **1441** (**FIGS. 56-64**; **70, 71, 77, 78**), or positioner **2017** (**FIGS. 122-126**), **2090** (**FIGS. 110-118**), **2122** (**FIGS. 95, 96, 103-109**) and **2168** (**FIGS. 83, 84, 89-94**) (all of which are described below)), providing a transversely retractable and extendible device useful for, referring to **FIG. 2**, insertion in a retracted position in a retrograde direction through the urethra **5** and into bladder opening **4**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned; or alternatively, insertion in a retracted position in an antegrade direction through an incision in the abdomen and an upper surface of the bladder **1**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned. Generally, the positioner assembly may comprise and make use of any number of alternately extendable and retractable projections, petals, arms, claws, or other grasping or catching members for catching and gaining control of bladder wall **2** surrounding bladder opening **4**. The positioner assembly may have at least one member operably connected to a longitudinal member of the instrument and alternately transversely extendable from and retractable toward the longitudinal axis thereof in response to input by a surgeon at a proximal end of the instrument.

[**0268**] Alternatively, it can be appreciated by one skilled in the art that when an anchor driver assembly is included with the instrument, that is functional to open and subsequently drive anchors through the bladder wall and into the pelvic floor as described herein, the positioner assembly or positioner petals as shown may be dispensed with in some circumstances. For example, referring to **FIGS. 25 and 26**, it can be appreciated that anchor driver pins **376** and anchors **700**, when opened within the bladder lumen and drawn downwardly until the distal ends of anchors **700** contact and possibly puncture bladder wall **2** surrounding bladder opening **4**, can be sufficient for use in capturing bladder wall **2** and drawing it downward into contact with, and securing it to, pelvic floor **7**, with bladder opening **4** and urethra opening **6** aligned, without the need for reverse positioner petals **930** as shown, in some circumstances. Thus, driver pins **376** with anchors **700** may serve a dual function as a positioner and as an anchor driver assembly.

Balloon/Harness Embodiment

[**0269**] **FIGS. 55-64** depict another embodiment of a method and instrument in accordance with the present invention (shown in an antegrade configuration), the instrument having a handle assembly **1100**, a straight tube assembly **1200**, a curved tube assembly **1300**, and an end effector assembly **1400**. In one embodiment of the present invention, instrument **1000** may be endo-scopically inserted into the abdominal cavity of a patient to effect an anastomosis between the urethra and bladder of a patient, thereby re-establishing the fluid connection between bladder **1** and the urethra **5**.

[**0270**] **FIG. 56** depicts curved tube assembly **1300** and end effector assembly **1400** after insertion into the bladder lumen **8** of a patient through an opening in the abdomen and upper surface of the bladder (not shown). The openings may be made, and abdominal insertion of the instrument may be accomplished by, for example, inserting a cannula with a trocar (not shown) into the abdomen and guiding it to and through an upper surface of the bladder in a generally antegrade direction, withdrawing the trocar, and inserting the instrument through the cannula and into the bladder lumen. Curved tube assembly **1300** may be flexible and may be provided with a bias at a bend angle (from about approximately 55 degrees to about approximately 90 degrees may be suitable) to provide curvature that may be desirable for inserting end effector assembly **1400** into the urethra **5** and actuating the instrument in an antegrade procedure. The bend angle of curved tube assembly **1300** may vary depending upon the particular needs of the procedure or surgeon utility.

[**0271**] **FIG. 57** depicts end effector assembly **1400** with opened positioner arms **1441** inside the bladder lumen **8**. Following the insertion of balloon assembly **1410** into bladder opening **4**, distal positioner tube **1445** has been moved downwardly and distally, causing positioner arms **1441** to open to positions transverse to the longitudinal axis of end effector assembly **1400**. Positioner arms **1441** are adapted to be effective for use in catching and urging bladder wall **2** surrounding bladder opening **4** toward pelvic floor **7** surrounding urethra opening **6**.

[**0272**] **FIG. 58** depicts the end effector assembly with anchor driver assembly **1460** opened inside the bladder lumen. During the insertion of end effector assembly **1400** into the bladder to the position shown in **FIG. 56**, the anchor pivot arms **1461** of anchor driver assembly **1460** are sheathed by anchor closing collar **1330** and are restrained in a closed position lying along distal positioner tube **1445**, as may be seen by comparing **FIGS. 57 and 58**. When anchor closing collar **1330** is moved upwardly with respect to distal

anchor driver tube **1450**, the anchor pivot arms **1461** are unsheathed, allowing them to swing outwardly, under spring bias, to the position shown in **FIG. 58**, bringing anchors **700** into a position reading for driving.

[**0273**] **FIG. 58** further illustrates positioning of the distal balloon assembly **1410** in the urethra opening **6**. Locating the urethra opening **6** with end **1413** and inserting end **1413** into the urethra opening **6** ensures that when the positioner arms **1441** contact and urge the bladder wall **2** toward the pelvic floor **7**, the urethra opening **6** and the bladder opening **4** will be substantially aligned.

[**0274**] **FIG. 59** illustrates the positioning of end effector assembly **1400**, bladder wall **2**, and pelvic floor **7** after instrument **1000** has been urged downward, thus causing positioner arms **1441** to urge bladder wall **2** downward into contact with pelvic floor **7**, which may be accomplished by pushing the entire instrument toward the pelvic floor. As bladder wall **2** surrounding bladder opening **4** is urged into contact with pelvic floor **7** surrounding urethra opening **6**, balloon assembly **1410** is urged into urethra opening **6**

[**0275**] **FIG. 60** illustrates the instrument after anchors **700** of anchor driver assembly **1460** have been driven through the bladder wall **2** into the pelvic floor **7** to secure bladder wall **2** surrounding bladder opening **4** in contact with pelvic floor **7** surrounding urethra opening **6**, with bladder opening **4** and urethra opening **6** substantially aligned. Once in the opened and ready position, as shown in **FIG. 58**, the anchors **700** may be driven through the bladder wall into the pelvic floor by moving distal anchor driver tube **1450** in a distal direction (toward the distal end of the instrument), which correspondingly moves the anchor pivot arms **1461**, anchor driver pin bases **1462**, anchor driver pins (concealed within anchors **700** as shown), and thus anchors **700**. Driving anchors **700** through bladder wall **2** and into pelvic floor **7** positions the distal portion of balloon assembly **1410** within the urethra **5** to insure that anchors **700** are installed such that the bladder opening **4** and the urethra opening **6** remain substantially aligned.

[**0276**] **FIG. 61** illustrates the instrument after withdrawal of anchor driver pins **1463** from the installed anchors **700** that are now lodged in the pelvic floor **7** to secure the bladder wall **2** to the pelvic floor **7**. Anchors **700** may be provided with barbs or other suitable structures adapted to lodge anchors **700** in tissues. As such, when anchor driver assembly **1460** is withdrawn by remotely pulling distal anchor driver tube **1450** while holding distal positioner tube **1445** substantially stationary, anchors **700** remain lodged in the tissue. Prior to use of the instrument, anchors **700** have been pre-loaded and may be releaseably held on the anchor driver pins **1463** by a friction fit or any other suitable means which will allow release when anchors **700** are lodged in tissues and anchor driver pins **1463** are withdrawn therefrom.

[**0277**] **FIG. 62** illustrates the end effector assembly **1400** after it has been partially retracted so as to situate the proximal portion of the balloon assembly **1410** within the bladder lumen **8**. As the end effector assembly **1400** is retracted, harness **1430** is unfolded and exposed. Harness **1430** may be integral with harness collar **1433** and may be affixed to anchors **700** at the anchor heads **710** with an anchoring loop, that may consist of suture material, running through both the anchor head **710** and the harness **1430**. As the end effector assembly **1400** is retracted, harness **1430** becomes unfolded as the harness collar **1433** is moved upward. End effector assembly **1400** may be retracted until harness **1430** resists retraction as a result of the attachment of harness **1430** to the anchor heads **710**.

[**0278**] **FIG. 63** illustrates the instrument after the positioner arms **1441** of the positioner assembly **1440** have been closed by retracting the positioner tube **1445** away from the pelvic floor **7**, and after the anchor pivot arms **1461** have been closed by moving anchor closing collar **1330** towards the pelvic floor while holding catheter tube **1420** and distal anchor driver tube **1450** substantially stationary. As will be apparent to a person of ordinary skill in the art, the steps of closing the positioner arms **1441** and closing the anchor pivot arms **1461** may be accomplished at any suitable time or sequence during the procedure.

[**0279**] **FIG. 64** illustrates the anchor driver assembly **1460** and the positioner assembly **1440** after their withdrawal from the bladder **1** has been commenced. Removing anchor driver assembly **1460** and positioner assembly **1440** leaves behind catheter tube **1420**, in communication with balloon assembly **1410**, also left behind. Catheter tube **1420** may be a catheter that is left in place until anastomosis is complete, to enable drainage of urine during recovery and healing.

[**0280**] **FIG. 65** illustrates balloon **1411** of balloon assembly **1410** after it has been inflated by pumping gas or fluid through an inflation lumen **1423** in catheter tube **1420** (see **FIGS. 67, 68**). Balloon **1411** may be inflated until it is restrained by harness straps **1432**, which then press balloon **1411** against the tissue surrounding bladder opening **4** so as to apply sufficient pressure to maintain contact between bladder wall **2** surrounding bladder opening **4** and pelvic floor **7** surrounding urethra opening **6**, to effect knitting of the respective tissues and thus effect anastomosis.

[**0281**] During recovery and healing, urine from the patient's bladder may be drained through drainage holes **1421** that are in communication with a urine drainage lumen **1422** in catheter tube **1420** (see **FIGS. 67, 68**). Drainage holes **1421** may be positioned, for example, distally on the catheter tube **1420**, or in any other suitable location. Suitable gas or fluid pressure within balloon **1411** may be maintained until the anastomosis is complete, by monitoring and adjusting the pressure within balloon **1411** through inflation lumen **1423**. The possibility of pressure necrosis in the tissues beneath the balloon may be reduced by including, for example, ribs **1415**, or other bumps, nodules, projections, or other features on the underside of balloon **1411**, which may be effective to reduce the loss of blood flow to tissue in contact with balloon **1411**. These features may be solid or of uniform wall thickness.

[**0282**] Additionally, balloon **1411** may be designed with features that effect the shape that it assumes upon inflation, and thus, effect the shape and area of the lower surface of balloon **1411** that contacts the bladder wall **2** upon inflation. For example, balloon **1411** may be designed and manufactured so as to have walls that are thicker on an upper portion and thinner on a lower portion, so that the lower portion of balloon **1411** is predisposed to expand downwardly and outwardly between the harness straps, and thereby present a larger surface area to contact the bladder wall **2**. Alternatively, balloon **1411** may be designed with features that cause it to assume a specific advantageous shape upon inflation.

[0283] Balloon assembly **1410**, harness **1430**, and catheter tube **1420** may removed from the patient by removing the harness anchoring loop **1435** attachment from the anchor heads **710** and harness straps **1432**. As shown in **FIG. 66**, harness straps **1432** may be affixed to the anchor heads **710** by one or more harness anchoring loops **1435** that pass through holes located in both the harness straps **1432** and the anchor heads **710**. As may be appreciated from **FIGS. 66-69**, free ends of harness anchoring loops **1435** may extend through catheter tube **1420** to its proximal end. Thus, the balloon assembly **1410** may be removed by pulling harness loop plug **1485** attached to one free end of each of harness anchoring loops **1435** and pulling the harness loop plug **1485** until the harness anchoring loops **1435** are completely removed from the instrument. Removing the harness anchoring loops **1435** from anchor heads **710** and harness straps **1432** disassociates the anchors **700** from the harness **1430** allowing the balloon assembly **1410** to be retracted. **FIG. 67** illustrates anchoring loop passages **1436** where, in one embodiment of the present invention, harness anchoring loops **1435** may pass through the anchoring loop passage **1436** into the anchoring loop lumens **1424** of catheter tube **1420** (**FIG. 68**). Harness anchoring loops **1435** may comprise suture material.

[0284] **FIGS. 67 and 68** illustrate an embodiment of a method and configuration of an instrument adapted to enable inflation of balloon **1411** of balloon assembly **1410** in accordance with the present invention. Catheter tube **1420** may include an inflation lumen **1423** that extends distally through the balloon assembly body **1412**. An inflation port **1414** provides a passageway between inflation lumen **1423** and the balloon cavity to enable inflation, deflation and balloon pressure regulation. Gas or fluid pressure, provided and regulated through inflation lumen **1423** may pass through inflation port **1414** to adjust and regulate the pressure within the balloon **1411** as may be desired to affect the pressure the balloon exerts on the tissues. In one embodiment of the present invention, balloon **1411** may be expanded until restricted by harness straps **1432** of harness **1430**. Balloon **1411** may be constructed from an elastomeric material that fully encircles the balloon assembly body **1412**. The proximal and distal portions of balloon **1411** may be glued or otherwise adhered to the balloon assembly body **1512** by any suitable means.

[0285] **FIG. 68** illustrates an embodiment of a catheter tube **1420** in accordance with the present invention having a urine drainage lumen **1422**, at least one anchoring loop lumen **1424**, and an inflation lumen **1423**. It will be apparent to one of ordinary skill in the art that various types of lumens are within the scope of the present invention and that the lumens or catheter cross sections described may be maintained within a single catheter or housed separately depending on the needs of the user. Catheter tube **1420** may be any suitable diameter.

[0286] **FIG. 69** illustrates an embodiment of the proximal end of a catheter tube **1420** as may be connected to a urine collection bag **1500**. Gas or fluid may be delivered through backflow stop valve **1483** located in the collection bag (as shown) and/or in the catheter. This may be accomplished by, for example, applying sufficient positive pressure to open backflow stop valve **1490**, or by inserting a needle through the valve to apply pressure.

[0287] Still referring to **FIGS. 68 and 69**, a catheter cap **1480** is provided, connected to urine collection bag **1500** via urine tube **1482**. Urine tube **1482** may be provided with a urine backflow stop valve **1483** to prevent urine backflow. Catheter cap **1480** may be removably attached to catheter tube **1420** by, for example, threads **1481**.

[0288] **FIGS. 66-69** illustrate a way in which one or more harness anchoring loops **1435** may be routed and contained within an instrument, and within a tube such as, for example, catheter tube **1420**. Those skilled in the art will appreciate that other configurations are possible, as are other ways of attaching and detaching anchor heads **710** with a harness strap **1432**. Catheter tube **1420** may be constructed from any material that is substantially biocompatible or suitable for use within the human body such as, for example, latex, other suitable polymers, nitinol, or combinations thereof.

[0289] Referring to **FIGS. 58, 59, 64** and **70**, catheter tube **1420** may be located within distal positioner tube **1445** and positioner assembly **1440**. The distal end of positioner assembly **1440** may abut harness collar **1433** of harness **1430**. Positioner arms **1441** of the positioner assembly **1440** are opened when the distal positioner tube **1445** is driven in a distal direction with respect to catheter tube **1420**, compressing positioner assembly **1440** longitudinally against harness collar **1433**. Distal positioner tube **1445** may be coupled with the positioner assembly **1440** by, for example, a pin or other suitable attachment mechanism.

[0290] Referring to **FIGS. 58, 59, 63, 64** and **70**, distal positioner tube **1445** may be located within distal anchor driver tube **1450**. When the anchor pivot arms **1461** are opened (as shown in **FIGS. 58 and 59**), the distal anchor driver tube **1450** may be moved to drive the anchor driver assembly **1460** distally (and thus, in use, downward towards the pelvic floor), so as to drive the anchors **700** through the bladder wall **2** and into the pelvic floor **7**. Distal anchor driver tube **1450** is coupled with anchor pivot arm yoke **1467** of anchor driver assembly **1460**. Anchor pivot arm yoke **1467** may be coupled with the anchor pivot arms **1461** by, for example, pins, or any other suitable means, and biased to swing outwardly by anchor pivot arm springs **1466** or other suitable biasing means. The anchor pivot arms **1461** may be hingeably coupled with an anchor driver pin base **1462** with an affixed anchor driver pin **1463**. Pins, or any other suitable attachment means permitting swinging movement, may be used to couple the anchor driver pin base **1462** to the anchor pivot arm **1461**, and anchor pivot arm **1461** and driver pin base **1462** may have suitable cooperating shapes that limit the range of relative swinging movement between them to a suitable angle as may be appreciated from **FIG. 59**. Anchor pivot arm springs **1466** may be included to bias anchor pivot arms **1461** toward an open position shown in **FIG. 59**. Anchor driver assembly **1460** may be brought to a closed position (shown in **FIG. 63**), with anchor pivot arms **1461** lying substantially alongside distal positioner tube **1445**, by moving anchor closing tube **1220** distally, which correspondingly pushes ribbed flex tube **1325** and anchor closing collar **1330** distally, with respect to distal anchor driver tube **1450**, causing anchor closing collar **1330** to contact anchor pivot arms **1461**, urge them to a closed position, and then sheath and restrain them. This motion is reversed in order to permit anchor pivot arms **1461** to open.

[0291] Distal anchor driver tube **1450** may be substantially coaxially located within curved spine tube **1305**. Curved

spine tube **1305** functions as a portion of a skeleton, on, in or about which the other components reside and move. It may be desirable for purposes of manipulability and use of the instrument that curved spine tube **1305** be substantially rigid, or somewhat flexible, and it may be formed of nitinol, or any other material having the desired properties.

[**0292**] Still referring to **FIGS. 59, 63, 64** and **70**, curved spine tube **1305** may be located within flex tube **1325**. Flex tube **1325** may be constructed from any suitable material such as, for example, a substantially biocompatible polymer having sufficient flexibility to permit the longitudinal movement of flex tube **1325** over and with respect to curved spine tube **1305**. Flex tube **1325** may be provided with ribs, as shown, or other suitable features that impart or increase flexibility. Flex tube **1325** may be affixed at its proximal end to anchor closing tube **1220** via flex tube coupling **1225**, and affixed at its distal end to anchor closing collar **1330**, by a pin or other suitable attachment means. Anchor closing collar **1330** may be adapted to contact, urge closing of, and sheath and restrain anchor pivot arms **1461**. Thus, anchor pivot arms **1461** and thus anchor driver assembly **1460** may be placed in a closed position by moving anchor closing tube **1220** distally, and placed in an open position by moving anchor closing tube **1220** proximally, with respect to distal anchor driver tube **1450**.

[**0293**] **FIG. 71** is a partial cross-sectional view, taken through the central axis of the distal end of the instrument shown in **FIG. 55**, illustrating particular exemplary components of the anchor and positioner assemblies of the instrument and the manner in which they may be connected to actuating tubes. Distal positioner tube **1445** is the innermost tube shown in **FIG. 71**, and terminates at positioner proximal collar **1442**, with which it may be made integral by suitable means. Positioner arms **1441** are hingeably affixed to positioner proximal collar **1442** at their proximal ends, and to positioner distal collar **1443** at their distal ends. It will be understood from examination of **FIGS. 64 and 70** that catheter tube **1420**, not shown in **FIG. 71**, may be located inside distal positioner tube **1445**, positioner distal collar **1442**, and positioner proximal collar **1443**, when the instrument is completely assembled. It will also be understood from **FIGS. 64 and 70** that harness collar **1433** is located on catheter tube **1420** adjacent to positioner distal collar **1443**, when the instrument is completely assembled. Referring again to **FIG. 71**, it can be understood that distal longitudinal movement of distal positioner tube **1445**, with respect to and toward harness collar **1433**, causes longitudinal compression of positioner assembly **1440** against harness collar **1433**, which in turn causes positioner arms **1441** to open outwardly from and transversely to the longitudinal axis of the assembly as shown partially in **FIG. 71**, toward fully opened positions that may be seen in **FIGS. 58-62**. The construction of positioner assembly **1440** in this embodiment may be seen in more detail in **FIG. 78**. It can be seen that longitudinal compression of positioner assembly **1440** causes positioner arms **1441** to extend outwardly as enabled by their shapes and hinges **1444** between proximal and distal segments of positioner arms **1441**. As shown, positioner assembly **1440** may include positioner proximal collar **1442**, positioner arms **1441**, and positioner distal collar **1443**, may be a single unitary part formed of a substantially biocompatible and flexible polymeric material suitable to allow integral hinges **1444** to flex as shown when opening of bladder assembly **1440** is required, and to return to an unflexed position when closing of the positioner assembly **1440** is required.

[**0294**] Referring to **FIGS. 58 and 59**, in an open position, positioner assembly **1440** is adapted to be useful for catching at bladder opening **4** and urging bladder wall **2** thereabout downwardly into contact with pelvic floor **7**. Positioner assembly **1440** may comprise the embodiment shown or any other suitable mechanism that transversely extends one or more members that will catch in bladder opening **4** and be useful for urging the bladder wall downwardly into contact with the pelvic floor, in response to force and movement translated from input from the surgeon at the proximal portion of the instrument, and then retracts or closes such members in response to force and movement translated from input from the surgeon, when it is desired that the mechanism be withdrawn.

[**0295**] Referring again to **FIG. 71**, distal anchor driver tube **1450** may be affixed to, and integral with, anchor pivot arm yoke **1467**. Anchor pivot arms **1461** may be attached to pivot arm yoke **1467** by pins as shown or other suitable means, and biased to swing outwardly by springs **1466**. The angle through which anchor pivot arms **1461** may swing outwardly may be restricted by suitably cooperating shapes of pivot arm yoke **1467** and anchor pivot arms **1461**. Anchor driver pin bases **1462** may be pivotably attached to anchor pivot arms **1461** by pins as shown or other suitable means. The angle through which anchor driver pin bases **1462** may move with respect to anchor pivot arms **1461** may be restricted by suitably cooperating shapes of anchor pivot arms **1461** and pin bases **1462**. Anchor driver pins **1463** are affixed to pin bases **1462** and may be integral therewith.

[**0296**] Anchors **700** may be hollow so as to fit onto anchor driver pins **1463** and be releasably held thereon by friction fit or any other suitable releasable means. Anchors **700** may have hollow bores within, opening at their heads, and extending substantially within their lengths, and driver pins **1463** may extend within such bores substantially the entire lengths thereof, so that the distal ends of driver pins **1463** may apply driving force proximate to the forward ends of anchors **700**, so as to prevent anchors **700** from buckling or veering off-direction as they might otherwise do if driven at their rearward ends. When anchors **700** are inserted into tissues, barbs thereon, or any other suitable lodging structures, cause anchors **700** to lodge in the tissues. Following insertion of anchors **700** in tissues, anchor driver pins **1463** may then be retracted from anchors **700** by retracting distal anchor driver tube **1450**. It will be appreciated that it may be desirable that distal anchor driver tube **1450** be flexible. Distal anchor driver tube **1450** may be formed from any suitable material such as, for example, nitinol. The anchor pivot arm springs may be for example, leaf springs, or any other suitable biasing device for biasing anchor driver assembly **1460** in an open position when unsheathed by anchor closing collar **1330**.

[**0297**] Still referring to **FIG. 71**, anchor closing collar **1330** may be integrally affixed to the distal end of flex tube **1325**. Referring to **FIG. 70**, the proximal end of flex tube **1325** may be integrally affixed to anchor closing tube **1220** via flex tube coupling **1225**. Referring again to **FIG. 71**, flex tube **1325** and integral anchor closing collar **1330** are not affixed to, and longitudinally movable with respect to,

anchor pivot arm yoke **1467** and curved spine tube **1305**. Thus, it can be appreciated that distal longitudinal movement of anchor closing tube **1220**, with distal anchor driver tube **1450** held stationary, can cause corresponding distal longitudinal movement of anchor closing collar **1330**, causing it to contact anchor pivot arms **1461**, urge them to a closed position lying substantially alongside distal positioner tube **1445**, and sheath and restrain them, in positions that may be seen, for example, in **FIGS. 57 and 63**. Conversely, moving anchor closing tube **1220** in a proximal direction, with distal anchor driver tube **1450** held stationary, pulls anchor closing collar **1330** up and off anchor pivot arms **1461**, allowing them to spring to an opened position shown, for example, in **FIGS. 58 and 71**.

[**0298**] Distal positioner tube **1445** and distal anchor driver tube **1450** are not affixed to one another, and therefore, may be longitudinally moved with respect to each other. This enables, for example, distal anchor driver tube **1450** to be moved distally while distal positioner tube is stationary, as would occur when anchors **700** are being driven through a bladder wall held stationary and in contact with a pelvic floor, by positioner assembly **1440**.

[**0299**] **FIG. 72** illustrates an exemplary configuration of a transition assembly that can be effective for translating relative force and movement of/between actuating members of a handle assembly **1100** to actuating members of an end effector assembly **1400**, such as shown in **FIG. 55**. Distal positioner tube **1445** is integral with positioner tube coupling **1206**, which is in turn integral with straight positioner tube **1209**, which is operatively connected with handle assembly **1100** as may be seen in **FIGS. 55, 72** and **77**. Thus, longitudinal force and movement in straight positioner tube **1209** effected by the handle assembly is directly translated to distal positioner tube **1445** via positioner tube coupling **1206**. Referring again to **FIG. 72**, distal anchor driver tube **1450** is integral with anchor driver tube coupling **1207**, which is in turn integral with straight anchor driver tube **1208**, which is operatively connected to handle assembly **1100** as may be seen in **FIGS. 55, 72** and **81**. Thus longitudinal force and movement in straight anchor driver tube coupling **1207** effected by the handle assembly is directly translated to distal anchor driver tube **1450** via anchor driver tube coupling **1207**. Referring to **FIGS. 72 and 82**, curved spine tube **1305** is integral with spine **1201**, which is in turn integral with handle housing **1101**, and thus curved spine tube **1305**, spine **1201** and handle housing **1101** form the instrument's relative stationary skeleton about which the actuating components move. As may be seen in **FIGS. 73 and 74**, spine tube **1201** may be integrally fitted and affixed to the handle housing by a spine retainer structure **1190** or other suitable structure integral with the handle housing. Finally, still referring to **FIG. 72**, and also **FIGS. 55 and 79**, flex tube **1325** is integral with flex tube coupling **1225** and anchor closing tube **1220**, which is operatively connected to handle assembly **1100**. Thus, longitudinal force and movement in anchor closing tube **1220** effected by the handle assembly is directly translated to flex tube **1325** and thus anchor closing collar **1330**. It will be apparent to a person of ordinary skill in the art that the configuration of components illustrated in **FIG. 72** is only an example by which force and movement in components effected by a handle assembly may be translated to components in an end effector, and that this translation may be accomplished in a variety of ways in accordance with the present invention.

[**0300**] **FIG. 82** depicts an exemplary structure that may be incorporated into the instrument to provide a skeletal ("ground") structure about which other components move and are actuated, and which can provide a structure to support manipulation of the entire instrument as a unit. As previously noted, curved spine tube **1305** is integral with spine **1201**. Spine **1201** is integral with handle housing **1101**. These three components are, thus, substantially integral. Housing **1101** may be molded or formed of a suitable rigid polymeric material. It may be desirable that spine **1201** and curved spine tube **1305** be substantially rigid, and have suitable stiffness and strength to support exertion of manipulative forces by the surgeon upon the instrument necessary to insert the instrument into a patient's abdomen, locate the bladder opening, urge the bladder into contact with the pelvic floor, and hold the bladder in contact with the pelvic floor during actuation of the instrument to drive anchors. Spine **1201** and curved spine tube **1305** may be formed of stainless steel, nitinol or any other suitable material. Curved spine tube **1305** may be affixed or joined to spine **1201** by any suitable means including but not limited to pins, welding, press fitting, cooperating threads, adhesives, etc. Spine **1201** may be affixed or joined to housing **1101** by any suitable means.

[**0301**] **FIGS. 73, 74, 79** and **80** illustrate an exemplary mechanism that may be incorporated into a handle assembly, by which an anchor closing tube **1220** may be alternately, selectively, longitudinally moved in proximal or distal directions and held so as to alternatively, selectively, open or close an anchor assembly to alternate positions shown, for example, in **FIGS. 57 and 58**. Anchor closing tube **1220** may be coupled with closing tube latching collar **1180** by pins as shown in **FIG. 80** or any other suitable means so that the two components move together longitudinally as a unit. Closing tube latch base **1179** may be integral with handle housing **1101**, and thus may be part of the instrument's skeleton. Closing tube latching collar **1180** freely rides upon closing tube spindle **1183**, which assures suitable alignment of closing tube latching collar with latch base **1179**, and supports a proximal end of closing tube spring **1181**. Closing tube latching collar **1180** includes latch members **1182** adapted to interact with cooperating features of closing tube latch base **1179** so as to alternately, selectively, be pushable proximally and rotatable to latch and be longitudinally restrained within latch base **1179** in the position shown in **FIG. 74**, or rotatable to unlatch and be released from latch base **1179** to assume the position shown in **FIG. 75**. When in a position released from latch base **1179**, closing tube latching collar **1180** is biased toward a distal position by closing tube spring **1181**. Closing tube latching collar **1180** may be restrained from disassociating distally from closing tube spindle **1183** by cooperating rims or lips or any other suitable means (not shown). Thus, it can be appreciated that by the exemplary configuration of components shown, anchor closing tube **1220** is biased in a distal position (thus, biasing anchor closing collar **1330** in a distal position holding anchor driver assembly **1460** in a closed position through exemplary mechanisms described above) by closing tube spring **1181**. When the surgeon wishes to open the anchor assembly, he or she may push closing tube latching collar **1180** proximally with respect to the handle housing until closing tube latching members **1182** engage with cooperating features of closing tube latch base **1179**, and then turn closing tube latching collar **1180** to latch into

closing tube latch base **1179**. This pulls anchor closing tube **1220** proximally, pulling anchor closing collar **1330** proximally to release the anchor pivot arms into an opened position.

[**0302**] **FIGS. 75-77** illustrate an exemplary mechanism that may be incorporated into the instrument to effect and translate force and movement to open and hold open a positioner assembly in accordance with the present invention. Positioner lever **1110** is pivotably mounted on, and may pivot about, axle **1113** which is integral with housing **1101**. Positioner lever **1110** has a longer portion and a shorter portion; the shorter portion has thereon positioner lever teeth **1111**. Positioner tube actuator rack **1160** rides longitudinally between guides or a track integral with housing **1101**, and is longitudinally movable proximally and distally. Positioner tube actuator rack **1160** has teeth **1159** thereon. Positioner lever **1110** and positioner tube actuator rack **1160** are situated such that positioner tube actuator rack teeth **1159** and positioner lever teeth **1111** are enmeshed. Thus, with respect to **FIGS. 75-77**, it can be appreciated that counterclockwise angular movement of positioner lever **1110** about axle **1113** is translated to distal linear movement of positioner tube actuator rack **1160**, and vice versa. The distal end of positioner tube actuator rack **1160** may be coupled with straight positioner tube **1209** by cooperating rims or lips forming an annular collar or other suitable means, such that the two parts move longitudinally together as a unit, and straight positioner tube **1209** may be made integral with distal positioner tube **1445** via positioner tube coupling **1206** as previously described. Thus, it can be appreciated that when a surgeon holding handle assembly **1100** pulls or squeezes positioner lever **1110**, distal positioner tube **1445** is urged distally. Referring to **FIG. 77**, it can be appreciated that when the entire instrument is assembled and positioner distal collar **1443** is restrained distally by a balloon assembly (see, e.g., **FIGS. 56, 57**), distal longitudinal movement of distal positioner tube **1445** causes longitudinal compression of positioner assembly **1440**, which causes positioner arms **1441** to open outwardly of the longitudinal axis, and vice versa. Positioner tube spring **1161**, in compression, biases positioner tube actuator rack **1160** toward a proximal position. Thus, it can be appreciated from **FIG. 77** that as a result, distal positioner tube **1445** is biased in a proximal position, allowing positioner arms **1441** and positioner assembly **1440** to assume a closed position. Driver/positioner locking lever **1170** is pivotably mounted on and pivots about pin **1176**, which may be integral with housing **1101**, and is biased by spring **1171**, in compression, in a counterclockwise direction (with respect to **FIG. 75**). Driver/positioner locking lever **1170** comprises a driver/positioner locking latch **1178**. When the handle assembly is assembled and ready for use, a lower surface of driver/positioner locking latch **1178** rests upon and is urged against an upper surface of the proximal end **1177** of positioner tube actuator rack **1160**. As positioner lever **1110** is pulled or squeezed in counterclockwise direction (with respect to **FIG. 75**), moving positioner tube actuator rack **1160** distally as previously described, a notch **1174** at the proximal end **1177** of positioner tube actuator rack **1160** moves beneath locking latch **1178** of driver/positioner locking lever **1170**, and locking latch **1178** moves into notch **1174** by urging of spring **1171**. This locks actuator rack **1160** into a distal position. As a result, as may be appreciated from **FIG. 77**, positioner arms **1441** and positioner assembly **1440** may be locked into an opened position. In order to then close positioner assembly **1440**, the surgeon may depress driver/positioner locking lever **1170**, which lifts locking latch **1178** out of notch **1174**, permitting positioner tube actuator rack **1160** to return to a proximal position under urging of spring **1161**.

[**0303**] **FIGS. 75, 76** and **81** illustrate an exemplary mechanism that may be incorporated into the instrument to effect and translate force and movement to drive an anchor assembly in accordance with the present invention. Anchor driver lever **1120** is pivotably mounted on, and may pivot about, axle **1113** which is integral with housing **1101**. Anchor driver lever **1120** has a longer portion and a shorter portion; the shorter portion has thereon anchor driver lever teeth **1121**. Anchor driver intermediate rack **1122** rides longitudinally between guides or a track integral with housing **1101**, and is longitudinally movable proximally and distally. Anchor driver intermediate rack **1122** has proximal teeth **1127** and distal teeth **1128** thereon. Anchor driver lever **1120** and anchor driver intermediate rack **1122** are situated such that anchor driver intermediate rack proximal teeth **1127** will engage anchor driver lever teeth **1121** when anchor driver lever **1120** is moved counterclockwise through a suitable angle (with respect to **FIG. 75**). Small anchor driver pinion **1123** and large anchor driver pinion **1124** are integral, and rotate about a pin supported by bosses in housing **1101**. Small anchor driver pinion **1123** and anchor driver intermediate rack are situated such that small anchor driver pinion **1123** is enmeshed with anchor driver intermediate rack distal teeth **1128**. Anchor driver rack **1125** rides longitudinally between guides or a track integral with positioner tube actuator rack **1160**, and a length and a distal end of anchor driver rack **1125** may extend into and be supported within spine **1201** as may be seen in **FIG. 75**. Anchor driver rack **1125** has anchor driver teeth **1129** thereon. Anchor driver rack **1125** and anchor driver lever **1120** are situated such that anchor driver teeth **1129** are enmeshed with large anchor driver pinion **1124**. The distal end of anchor driver rack **1125** is affixed by any suitable means to straight anchor driver tube **1208**. Thus, it may be appreciated from the foregoing, and examination of **FIGS. 75, 76** and **81**, that moving anchor driver lever **1120** so as to cause it to rotate counterclockwise (with respect to **FIGS. 75 and 81**) to the point where driver lever teeth **1121** mesh with proximal teeth **1127** on intermediate driver rack **1122**, will drive intermediate driver rack **1122** distally, which in turn, will cause small anchor driver pinion and large anchor driver pinion **1123** and **1124** to rotate counterclockwise, which, in turn, will drive anchor driver rack **1125**, straight anchor driver tube **1208**, anchor driver tube coupling **1207**, distal anchor driver tube **1450**, and thus, anchor driver assembly **1460**, distally. As may be appreciated from, for example, **FIGS. 59 and 60**, when the instrument is fully assembled and being used, this distal movement of anchor driver assembly **1460** drives anchors **700** into the tissues.

[**0304**] Positioner lever **1110** and anchor driver lever **1120** abut one another in side-by-side relationship, and both are mounted upon and pivot about axle **1113**. Positioner lever **1110** and anchor driver lever **1120** are formed so as to have cooperating features where they abut, such that counterclockwise movement of positioner lever **1110** effects corresponding counterclockwise movement of anchor driver lever **1120** (with respect to **FIG. 75**). Driver lever spring **1126**, in tension, is connected between a hook or other suitable attachment point in housing **1101** and an attachment

point on the shorter portion of anchor driver lever **1120** as shown. Thus, anchor driver lever **1120** is biased in a clockwise direction (with respect to **FIG. 75**).

[**0305**] Additionally, anchor driver lever **1120** is prevented from being depressed prior to activation of anchor positioner lever **1110**. Driver lever locking hook **1172** is pivotably mounted on and may rotate about a pin supported in housing **1101** as shown, and is biased in a counterclockwise direction by spring **1171** in compression, such that it hooks over a pin **1169** transversely protruding from the shorter portion of anchor driver lever **1120** at the position shown, preventing driver lever **1120** from moving counterclockwise (the pin is not directly shown; it protrudes from the back side of the component with respect to **FIG. 75**). However, when positioner lever **1110** is depressed, locking hook release member **1112** thereon engages locking hook **1172** and urges it in a clockwise direction (with respect to **FIG. 75**), which causes it to disengage from pin **1169**, thereby releasing anchor driver lever **1120** so that it may move in a counterclockwise direction.

[**0306**] Additionally, when the instrument is ready for use, but prior to deployment, anchor driver rack **1125** (and thus, anchor driver assembly **1460**) is locked in a proximal position, by engagement of locking latch **1178** of driver/positioner locking lever **1170**, with driver rack notch **1173**. When actuation of the instrument is begun by pulling and thereby rotating positioner lever **1110** counterclockwise, moving positioner tube actuator rack **1160** distally as previously described, a notch **1174** at the proximal end **1177** of positioner tube actuator rack **1160** moves beneath locking latch **1178** of driver/positioner locking lever **1170**, and locking latch **1178** moves into notch **1174** by urging of spring **1171**. As locking latch **1178** moves into notch **1174**, it moves out of driver rack notch **1173**, releasing driver rack **1125** so that it may be driven by pulling anchor driver lever **1120** as previously described.

[**0307**] Thus, it may be appreciated from the above description and from **FIGS. 73-82**, that when the instrument is assembled and made ready for use, positioner assembly **1440** is in a closed position, and anchor driver assembly **1460** is held closed by anchor closing collar **1330** and locked in a proximal position with respect to positioner assembly **1440**, placing the instrument in position to facilitate insertion into the patient. After insertion of the instrument into proper position within the patient with the end effector assembly within a lumen, actuation may be commenced by pulling positioner lever **1110** to the position in which it opens positioner assembly **1440** and is locked in such position by driver/positioner locking lever **1170** under urging of spring **1171**. When driver/positioner locking lever **1170** locks positioner lever **1110**, it simultaneously unlocks anchor driver rack **1125** by disengaging driver positioner locking latch **1178** from driver rack notch **1173**, freeing anchor driver rack **1125** to be driven in a distal direction. Anchor driver assembly **1460** may then be opened by pulling closing tube latching collar **1180** distally until it engages latch base **1179**, and rotating latching collar **1180** to latch into latch base **1179**. Anchor driver rack may then be driven in a distal direction (to drive anchors) by pulling anchor driver lever **1120**. After anchors are driven, spring **1126** in tension urges anchor driver lever **1120** to return, thus causing anchor driver rack **1125** and correspondingly anchor driver assembly **1460** to return to their original proximal positions (and pulling anchor driver pins out of anchors installed into tissues). Anchor driver assembly **1460** may then be returned a closed position by rotating and disengaging closing tube latching collar **1180** from latch base **1179**, which allows latching collar **1180** to return to its distal position urged by spring **1181**, moving closing collar **1330** distally and causing it to close anchor driver assembly **1460**. Finally, positioner assembly **1440** may be closed by depressing driver/positioner locking lever **1170**, which lifts driver/positioner locking latch **1178** from notch **1174** in the proximal end **1177** of positioner tube actuator rack **1160**, allowing positioner tube actuator rack **1160** to return to a proximal position under urging of positioner tube spring **1161**, closing positioner assembly **1440**. Thus, the instrument is returned to a closed position ready for withdrawal from the patient.

[**0308**] Referring to **FIGS. 55, 64, 65** and **75**, it may be appreciated that catheter tube **1420** may be routed through handle assembly **1100**, and through the entire instrument, to balloon assembly **1410**, where it may be affixed to harness collar **1433**. In one embodiment the catheter tube **1420** may extend proximally through the handle housing **1101** and out of the rear of the instrument **1000** as shown in **FIG. 75**. Anchor driver rack **1125** may be hollow, or may have a channel and "U"-shaped cross-section, and driver/positioner locking lever **1170** and handle housing **1101** may have suitable holes or other features, to accommodate passage of catheter tube **1420** therethrough. When the instrument is readied for use to install anchors, catheter tube **1420** may be releasably gripped at or within handle assembly **1110** by any suitable means so as to be held stationary with respect to handle housing **1101**, placing it in tension with respect to positioner assembly **1440** when positioner assembly **1440** is longitudinally compressed against harness collar **1433** to cause positioner assembly **1440** to open. After the instrument has been actuated to drive anchors and returned a closed position, catheter tube **1420** may then be released to permit withdrawal of all components except for catheter tube **1420** and balloon assembly **1410**, for use in completing the anastomosis procedure as described above.

[**0309**] Levers **1110**, **1120** and **1170** and positioner tube actuator rack **1160** may be formed of any material having suitable properties of strength, stiffness and formability or moldability, including polymeric materials.

[**0310**] Small anchor driver pinion **1123**, large anchor driver pinion **1124**, anchor driver intermediate rack **1122**, anchor driver rack **1125**, positioner tube actuator rack **1160** and driver lever locking hook **1172** may be made of any material having suitable strength for small mechanical components, including steel or highstrength polymers.

[**0311**] The above-described embodiment is only one example describing portions of an instrument that may be used for one or more of the bringing and holding of the bladder in contact with the pelvic floor with the openings in the bladder and urethra aligned, driving anchors through the bladder wall and into the pelvic floor and securing a harness within the bladder lumen, inflating a balloon within the harness and thereby applying pressure to the bladder wall to effect knitting of the bladder wall with the pelvic floor, and draining urine from the bladder during the time required for recovery and healing, to effect an anastomosis between the bladder and the urethra following a prostatectomy.

[**0312**] It will be appreciated by one skilled in the art that the components described above may have alternative con-

figurations and embodiments useful for effecting the same steps. It will be appreciated by one skilled in the art that the components described above may, alternatively, be designed and configured so as to be useful for effecting the above-described steps in a retrograde direction rather than an antegrade direction as described above.

[0313] It can be appreciated by one skilled in the art that the mechanism comprising the positioner assembly **1440** and performing the bladder positioning function thereof may have a variety of alternative configurations including but not limited to embodiments described herein (and thus including, without limitation, the positioner assembly **400**, shuttlecock assembly **800** with positioner petals **830** (**FIGS. 17-21**), umbrella assembly **900** with reverse positioner petals **930** (**FIGS. 22-27**), described above, or positioner **2017** (**FIGS. 122-126**), **2090** (**FIGS. 110-118**), **2122** (**FIGS. 95, 96, 103-109**) and **2168** (**FIGS. 83, 84, 89-94**) (all of which are described below)), providing a transversely retractable and extendible device useful for, referring to **FIG. 2**, insertion in a retracted position in a retrograde direction through the urethra **5** and into bladder opening **4**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned; or alternatively, insertion in a retracted position in an antegrade direction through an incision in the abdomen and an upper surface of the bladder **1**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned. Generally, the positioner assembly may comprise and make use of any number of alternately extendable and retractable projections, petals, arms, claws, or other grasping or catching members for catching and gaining control of bladder wall **2** surrounding bladder opening **4**. The positioner assembly may have at least one member operably connected to a longitudinal member of the instrument and alternately extendable transversely from and retractable toward the longitudinal axis thereof in response to input by a surgeon at a proximal end of the instrument.

[0314] Alternatively, it can be appreciated by one skilled in the art that when an anchor driver assembly is included with the instrument, that is functional to open and subsequently drive anchors through the bladder wall and into the pelvic floor as described herein, the positioner assembly or positioner arms as shown may be dispensed with in some circumstances. For example, referring to **FIGS. 58-61**, it can be appreciated that anchor driver pins **1463** and anchors **700**, when opened within the bladder lumen and pushed downwardly until the distal ends of anchors **700** contact and possibly puncture bladder wall **2** surrounding bladder opening **4**, can be sufficient for use in capturing bladder wall **2** and pushing it downward into contact with, and securing it to, pelvic floor **7**, with bladder opening **4** and urethra opening **6** aligned, without the need for positioner assembly **1400** as shown, in some circumstances. Thus, anchor driver assembly **1460** with anchors **700** may serve a dual function as a positioner and as an anchor driver assembly.

Alternative Balloon/Harness Embodiment

[0315] **FIG. 136** depicts another exemplary embodiment of an instrument **3000** of the present invention, adapted for use in effecting the anastomosis of the bladder and urethra tissues following a radical prostatectomy in accordance with a method of the present invention. The instrument may comprise a handle assembly **3100**, a tube assembly **3200** and an end effector assembly **3400**. End effector assembly **3400** is adapted to facilitate retrograde insertion into and through a patient's urethra **5** and into the bladder lumen **8** through bladder opening **4**. It will be understood by those skilled in the art that instrument **3000** can, alternatively, be designed and configured in an embodiment to be effective to perform steps substantially similar to those herein described via insertion from an antegrade direction, i.e., through incisions through the abdomen and an upper surface of the bladder (not shown), and downwardly through the bladder opening **4** and into urethra opening **6**. An example of such an embodiment is depicted and described in co-pending U.S. applications Ser. Nos. 60/639,836 and 60/582,302.

[0316] **FIG. 135** is a longitudinal cross-sectional view of end effector assembly **3400** after insertion into and through the patient's urethra **5** and into the bladder opening **4**. It can be seen that end effector assembly **3400** may comprise distal end cap assembly **3410**, balloon harness **3430**, anchor driver assembly **3460**, and positioner assembly **3440**. End effector assembly **3400** and the assemblies it comprises, just identified, may be operably connected to, and controlled by, handle assembly **3100** (shown in **FIG. 136**), via tube assembly **3200**, which may comprise spine tube **3210**, central rod or guide wire **3230**, inner positioner tube **3240**, outer positioner tube **3241**, anchor driver closing tube **3260** and anchor driver tube **3261**. These tubes and rod may be assembled so as to be substantially coaxial. Central rod or guide wire **3230** may pass through the length of the instrument within anchor driver closing tube **3260**, and may be affixed and made integral with end cap **3411** by any suitable means. Anchor driver closing tube **3260** may be longitudinally movable with respect to central rod or guide wire **3230**, and may be affixed and made integral with anchor closing collar **3464** by any suitable means. Anchor driver closing tube **3260** may be located within anchor driver tube **3261**, and may be longitudinally movable with respect thereto. Anchor driver tube **3261** may be affixed and made integral with anchor pivot arm yoke **3467** by any suitable means. Anchor driver tube **3261** may be located within inner positioner tube **3240**, and may be longitudinally movable with respect thereto. Inner positioner tube **3240** may be affixed and made integral with positioner distal collar **3443** by any suitable means. Inner positioner tube **3240** may be located within outer positioner tube **3241**, and may be longitudinally movable with respect thereto. Outer positioner tube **3241** may be affixed and made integral with positioner proximal collar **3442** and spine tube **3210** by any suitable means. Tubes **3210**, **3241**, **3240**, **3261** and **3260**, and rod **3230**, may be made of nitinol or any other material having suitable combined properties of strength, stiffness and biocompatibility as may be desirable for purposes of the present embodiment. The instrument also includes balloon harness **3430**, which is attached at a distal end to end cap assembly **3410**, and releasably attached at proximal ends to anchors **700**. Anchors **700** are releasably held by the instrument as will be described below. Use of the present embodiment of an instrument and method, in accordance with the present invention, and remaining components and operation thereof, for effecting anastomosis of a patient's bladder and urethra following a radical prostatectomy, will now be described.

[0317] As previously noted, and as shown in **FIG. 135**, end effector assembly **3400** may be inserted into and through the patient's urethra in a retrograde direction and into the bladder opening **4**, and then into the bladder lumen as may be appreciated from **FIG. 136**. **FIG. 136** depicts the end effector assembly after insertion completely into the bladder lumen **8**, after anchor driver assembly **3460** and positioner assembly **3440** have been opened for use, and after positioner assembly **3440** has been brought into contact with bladder wall **2** and used to urge the bladder wall **2** surrounding the bladder opening into contact with the pelvic floor **7**. To open the positioner assembly **3440**, the surgeon holds spine tube **3210** and outer positioner tube **3241** stationary, and withdraws inner positioner tube **3240** proximally, using handle assembly **3100** (shown in **FIG. 136**). This draws positioner distal collar **3443** toward positioner proximal collar **3442**. Positioner arms **3441** have upper segments hinged by any suitable means to positioner distal collar **3443** and lower segments hinged by any suitable means to positioner proximal collar **3442**, and also hinged together by any suitable means. Thus, drawing positioner distal collar **3443** toward positioner proximal collar **3442** in the manner described above causes positioner arms **3441** to fold outwardly and transversely with respect to the longitudinal axis of the instrument, as may be appreciated from a comparison of **FIGS. 135 and 136**.

[0318] Once positioner arms **3441** of positioner assembly **3440** are opened, the surgeon may manipulate the instrument to cause positioner arms **3441** to urge bladder wall **2** downward into contact with pelvic floor **7**, as may be appreciated from **FIG. 136**. It will also be appreciated from **FIG. 136** that the respective openings in the bladder and the urethra are aligned.

[0319] The surgeon may open the anchor driver assembly **3460** by holding anchor driver closing tube **3260** stationary while withdrawing anchor driver tube **3261** proximally, or, alternatively, by holding anchor driver tube **3261** stationary while advancing anchor driver closing tube **3260** distally, again, via use of handle assembly **3100** (shown in **FIG. 136**). As noted above, anchor pivot arm yoke **3467** is integral with anchor driver tube **3261**, and anchor closing collar **3464** is integral with anchor driver closing tube **3260**. Anchor pivot arms **3461** are pivotably connected to anchor pivot arm yoke **3467**, and are biased to swing outwardly by anchor pivot arm springs **3466**. As shown in **FIG. 135**, when anchor driver assembly **3460** is in a closed position, anchor closing collar **3464** sheaths and restrains anchor pivot arms **3461** in a retracted position. When anchor pivot arm yoke **3467** is urged proximally down and away from stationary anchor closing collar **3464**, or alternatively, when anchor closing collar **3464** is urged distally up and away from stationary anchor pivot arm yoke **3467**, anchor pivot arms **3461** are released from anchor closing collar **3464** and allowed to swing outwardly under urging of springs **3466**, as may be appreciated from a comparison of **FIGS. 135 and 136**. The angle at which anchor pivot arms **3461** swing outwardly as described above may be limited by, for example, suitable cooperating shapes of pivot arms **3461** and anchor pivot arm yoke **3467**, or, alternatively for example, by cooperating shapes and limiting the relative longitudinal travel between anchor closing collar **3464** and anchor pivot arms **3461**.

[0320] Referring to **FIG. 136**, it can be seen that anchor driver pin bases **3462** are pivotably connected to anchor pivot arms **3461**, and may be biased to swing inwardly with respect thereto by any suitable means, to assume a substantially downward orientation as shown in **FIG. 136**. Anchor driver pins **3463** may be affixed and made integral with anchor driver pin bases **3462**. Anchors **700** may be loaded onto anchor driver pins **3463** and held thereon by friction fit or any other suitable releasable means. Anchors **700** may include harness hooks **760** (as may be seen in greater detail in **FIG. 141**). As may be appreciated from a comparison of **FIGS. 135 and 136**, anchors **700** may be moved outwardly and into a position ready for driving by opening anchor driver assembly **3460** as described above.

[0321] Referring now to **FIGS. 136 and 137**, using handle assembly **3100** (see **FIG. 136**) the surgeon may drive anchors **700** downwardly through the bladder wall **2** and into tissues of the pelvic floor **7** by withdrawing anchor driver tube **3261**, which pulls anchor pivot arm yoke **3467**, and correspondingly, anchor pivot arms **3461**, anchor driver pin bases **3462**, anchor driver pins **3463**, and anchors **700**, downward. Anchor pivot arms **3461** and anchor driver pin bases **3462** may be situated on the instrument so that when driven downward, anchors **700** do not interfere with, and are driven down between, positioner arms **3441**. Anchors **700** may comprise barbs or other suitable lodging structures (not shown) on their shafts, so as to cause them to be lodged in and resist withdrawal from the tissues of the pelvic floor.

[0322] Referring now to **FIGS. 137 and 138**, the surgeon may retract the driver pins **3463** from the now-installed anchors **700**, by advancing anchor driver tube **3261** distally, which will move anchor pivot arm yoke **3467**, and correspondingly, anchor pivot arms **3461**, anchor driver pin bases **3462**, and anchor driver pins **3463**, distally upward. If anchors **700** are lodged or otherwise remain in the tissues of the pelvic floor **7**, anchor driver pins **3463** onto which anchors **700** are held by releasable means, will release from anchors **700**, leaving anchors **700** installed and lodged in the tissues as shown in **FIG. 138**.

[0323] Referring to **FIGS. 138 and 139**, again, using handle assembly **3100** (shown in **FIG. 136**), the surgeon may close the anchor driver assembly, and return it to its original position to facilitate withdrawal from the patient, by distally advancing anchor driver tube **3261** while holding anchor driver closing tube **3260** stationary. Alternatively, the surgeon may proximally retract anchor driver closing tube **3260** while holding anchor driver tube **3261** stationary. Either sequence will bring anchor pivot arm yoke **3467**, and correspondingly, anchor pivot arms **3461**, within anchor closing collar **3464**, causing anchor pivot arms **3461** to be moved upwardly and inwardly relative to anchor closing collar **3464** and be sheathed and restrained thereby, as depicted in **FIG. 139**.

[0324] In final preparation for withdrawal of anchor driver and positioner assemblies, referring to **FIGS. 139 and 140**, the surgeon may retract positioner arms **3441** by distally advancing inner positioner tube **3240** while holding outer positioner tube **3241** and spine tube **3210** stationary. This moves positioner distal collar **3443** distally and away from positioner proximal collar **3442**, drawing positioner arms **3441** inwardly to the position shown in **FIG. 140**.

[0325] With the anchor driver and positioner assemblies retracted to the positions shown in **FIG. 140**, the surgeon may withdraw these assemblies from the patient by with-

drawing, together as a group, spine tube **3210**, outer positioner tube **3241**, inner positioner tube **3240**, anchor driver tube **3261** and anchor driver closing tube **3260**, leaving behind end cap assembly **3410**, harness **3430** and anchors **700**, as may be seen by comparing **FIGS. 140 and 141**. Referring to **FIG. 141**, it can be seen that balloon harness **3430** has been attached to bladder walls **2** surrounding bladder opening **4**, which, in turn, may be held in contact with the tissues of pelvic floor **7** surrounding urethra opening **6**, by installed anchors **700**. Tails **3433** of harness **3430** may be held by anchors **700** by way of hooks **760** as shown or by any other suitable means. Central rod **3230** can now serve as a guide wire as will be described below, and may also be used to withdraw the remaining portions of the instrument following completion of the procedure.

[**0326**] It will be apparent to persons skilled in the art that a variety of mechanisms might be comprised by handle assembly **3100** and configured and adapted to transmit longitudinal (advancement and retraction) forces and movement to an end effector assembly **3400**, in order to effect and translate the forces and movement therein necessary to actuate the exemplary embodiments as described above.

[**0327**] **FIG. 146** shows end cap assembly **3410** and balloon harness **3430** in more detail. End cap assembly **3410** may comprise drainage extension **3413** having thereon harness attachment neck **3415** and one or more drainage holes **3414**. End cap assembly **3410** may also include snap-in collar **3412** and end cap **3411**, which may be integrally formed or assembled. End cap **3411** may be connected or affixed to and made integral with central rod or guide wire **3230** by any suitable means. Balloon harness **3430** may include attachment collar **3431**, to fit around harness attachment neck **3415** and be held thereon by their respective cooperating shapes and dimensions. Balloon harness **3430** may also includes tails **3433** having therein anchor hook holes **3432**, through which anchor hooks **760** may pass, thus attaching balloon harness **3430** to anchors **700** (see, again, **FIG. 141**). Balloon harness **3430** may be made of any suitable biocompatible polymer having properties of flexibility but effectively limited elasticity so as to render it suitable for remaining held in position and serving the balloon restraining function that will be described below.

[**0328**] Returning to **FIG. 141**, and also referring to **FIG. 142**, the next step in the exemplary method described herein is for the surgeon to insert balloon catheter assembly **3500** into the patient and into the balloon harness **3430** via central rod **3230**, serving as a guide wire.

[**0329**] Central rod **3230**, serving as a guide wire, may be provided with one or more markings along its length (not shown) that enable the surgeon to determine the distance that a balloon catheter assembly is inserted into the patient. By noting the length of the balloon catheter assembly and its position with respect to the one or more markings on central rod or guide wire **3230** after insertion, the surgeon can determine whether the catheter assembly has been inserted to the correct depth within the patient with respect to the harness and distal end cap assembly.

[**0330**] Referring to **FIGS. 142, 143** and **146**, balloon catheter assembly **3500** may comprise catheter tube **3510**, balloon **3520** attached thereto, and catheter end plug **3530**. Catheter tube **3510** may include inflation lumen **3511** and inflation port **3512**. Balloon **3520** may have proximal and distal portions attached in any substantially gas and/or fluid-tight manner at proximal and distal points on catheter tube **3510**, and may be ring-shaped upon inflation or otherwise have a central passage through which catheter tube **3510** passes, as may be appreciated from **FIG. 143**. Catheter end plug **3530** may comprise snap-in button **3531**, one or more drainage holes **3414**, and catheter tube insert **3534**, with stop collar **3535**.

[**0331**] Referring again to **FIG. 142**, upon insertion of balloon catheter assembly **3500**, snap-in button **3531** of catheter end plug **3530** cooperates with and snaps into snap-in collar **3412** of distal end cap assembly **3410**, and is held thereby. Referring to **FIGS. 142 and 143**, balloon **3520** may then be inflated, and have its internal pressure regulated, via inflation lumen **3511** and inflation port **3512** in catheter tube **3510**. Referring to **FIG. 143**, it may be seen that balloon **3520**, upon inflation, may expand outwardly between the straps of harness **3430**, and be used to exert pressure on the bladder walls **2** surrounding the bladder opening in order to, both, press bladder walls **2** into contact with the tissues of pelvic floor **7**, and seal off the bladder opening, pelvic floor and urethra from urine and other materials collecting in the bladder during recovery and healing. During recovery and healing, urine and other materials collecting in the bladder may be drained into catheter tube **3510** via drainage holes **3414** and **3533**, in distal end cap assembly **3410** and catheter end plug **3530**, respectively. During recovery and healing, catheter tube **3510** may be connected at a proximal end to a urine collection bag (not shown).

[**0332**] It may be appreciated that the combination of a harness structure anchored to the pelvic floor as depicted and described herein, constraining and holding the inflated balloon of a balloon catheter, has the desirable effect of constraining the catheter from substantial axial or longitudinal movement within the urethra during the period required for anastomosis.

[**0333**] Suitable gas or fluid pressure within balloon **3520** may be maintained until anastomosis is complete, by monitoring and adjusting the pressure within balloon **3520** through inflation lumen **3511**. About 1 to 6 p.s.i. pressure within the balloon may be suitable, and about 1.5 to 2.5 p.s.i. is preferred. The possibility of pressure necrosis in the tissues beneath the balloon may be reduced by including, for example, ribs or other bumps, nodules, projections, or other features (not shown) on the underside of balloon **3520**, which may be effective to reduce the loss of blood flow to tissue in contact with balloon **3520**. These features may be solid or of uniform wall thickness. Additionally, balloon **3520** may be designed with features that effect the shape that it assumes upon inflation, and thus, effect the shape and area of the lower surface of balloon **3520** that contacts the bladder wall **2** upon inflation. For example, balloon **3520** may be designed and manufactured so as to have walls that are thicker on an upper portion and thinner on a lower portion, so that the lower portion of balloon **3520** is predisposed to expand downwardly and outwardly between the harness straps, and thereby present a larger surface area to contact the bladder wall **2**. Alternatively, balloon **3520** may be designed and manufactured so as to have walls that are thicker on a lower portion and thinner on an upper portion, so that the upper portion of balloon **3520** is predisposed to inflate first, within the bladder lumen, and thereby draw the

remaining portion of the balloon up into the bladder lumen, and substantially out of the pelvic floor region, before the lower portion fully inflates. Alternatively, balloon **3520** may be designed with features that cause it to assume other specific advantageous shapes upon inflation to, for example, fill a large portion of the space defined by the harness straps.

[**0334**] In order to facilitate inflation and assist in maintaining suitable gas or fluid pressure within balloon **3520**, a two-way check valve may be installed along the inflation gas or fluid passage including inflation lumen **3511**. For example, a two-way check valve may comprise a "duckbill" type valve or other valve that functions to permit gas or fluid to pass into inflation lumen **3511** but prevents gas or fluid from passing back out, in conjunction with a pressure release valve that functions to permit gas or fluid to pass out of the system if pressure within balloon **3520** and/or the fluid passage exceeds a desired maximum amount.

[**0335**] **FIG. 144** depicts an alternative manner of attachment of balloon **3520** to the distal end of catheter tube **3510**. In comparison with balloon **3520** as depicted in **FIG. 143**, it can be seen in **FIG. 144** that the sheet-like material forming the upper wall of balloon **3520** has been attached to the distal end of catheter tube **3510** in inverted orientation, which may serve to enhance sealing at the attachment point and improve the balloon's ability to sustain gas or fluid pressure when inflated.

[**0336**] Following substantial completion of the anastomosis procedure, i.e., following substantial knitting of the tissues of the bladder walls and the pelvic floor surrounding the respective openings of the bladder and the urethra, the balloon may be deflated and the balloon catheter assembly **3500** withdrawn from the patient. This leaves behind the end cap assembly **3410**, harness **3430** and anchors **700**, as may be seen by comparing **FIGS. 144 and 145**. Following withdrawal of the balloon catheter assembly, end cap assembly **3410** and harness **3430** may be withdrawn from the patient by proximally withdrawing central rod or guide wire **3230** (shown in progress in **FIG. 145**). It can be seen in **FIG. 145** that the tails **3433** of harness **3430** may be removed from and released by harness hooks **760** of anchors **700** by inversion of the position of harness **3430**, and subsequent proximal tension exerted thereon, effected by withdrawing distal end cap assembly **3230**, causing harness tails **3433** to slide off attachment hooks **760**. Anchors **700** may be left behind in the patient.

[**0337**] As noted, central rod or guide wire **3230** may be attached to and made integral with end cap **3411** by any suitable means. When central rod or guide wire **3230** is made integral with end cap **3411**, it is substantially integral with the other components of end cap assembly **3410** as described herein, and thus also with attachment collar **3431** of balloon harness **3430**. As such, central rod or guide wire **3230** may be used for withdrawal of balloon harness **3430** following substantial completion of the anastomosis procedure.

[**0338**] The above-described embodiment is only one example describing portions of an instrument that may be used for one or more of the bringing and holding of the bladder in contact with the pelvic floor with the openings in the bladder and urethra aligned, driving anchors through the bladder wall and into the pelvic floor and securing a harness within the bladder lumen, inflating a balloon within the harness and thereby applying pressure to the bladder wall to effect knitting of the bladder wall with the pelvic floor, and draining urine from the bladder during the time required for recovery and healing, to effect an anastomosis between the bladder and the urethra following a prostatectomy.

[**0339**] It will be appreciated by one skilled in the art that the components described above may have alternative configurations and embodiments useful for effecting the same steps. It will be appreciated by one skilled in the art that the components described above may, alternatively, be designed and configured so as to be useful for effecting the above-described steps in an antegrade direction rather than a retrograde direction as described above.

[**0340**] It can be appreciated by one skilled in the art that the mechanism comprising the positioner assembly **3440** and performing the bladder positioning function thereof may have a variety of alternative configurations including but not limited to embodiments described herein (and thus including, without limitation, the positioner assembly **400**, shuttlecock assembly **800** with positioner petals **830** (**FIGS. 17-21**), umbrella assembly **900** with reverse positioner petals **930** (**FIGS. 22-27**), described above, or positioner **2017** (**FIGS. 122-126**), **2090** (**FIGS. 110-118**), **2122** (**FIGS. 95, 96, 103-109**) and **2168** (**FIGS. 83, 84, 89-94**) (all of which are described below)), providing a transversely retractable and extendible device useful for, referring to **FIG. 2**, insertion in a retracted position in a retrograde direction through the urethra **5** and into bladder opening **4**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned; or alternatively, insertion in a retracted position in an antegrade direction through an incision in the abdomen and an upper surface of the bladder **1**, extending or expanding within bladder lumen **8**, catching in bladder opening **4** and manipulating to urge bladder wall **2** surrounding bladder opening **4** into contact with pelvic floor **7** surrounding urethra opening **6** with the respective openings aligned. Generally, the positioner assembly may comprise and make use of any number of alternately extendable and retractable projections, petals, arms, claws, or other grasping or catching members for catching and gaining control of bladder wall **2** surrounding bladder opening **4**. The positioner assembly may have at least one member operably connected to a longitudinal member of the instrument and alternately extendable transversely from and retractable toward the longitudinal axis thereof in response to input by a surgeon at a proximal end of the instrument.

[**0341**] Alternatively, it can be appreciated by one skilled in the art that when an anchor driver assembly is included with the instrument, that is functional to open and subsequently drive anchors through the bladder wall and into the pelvic floor as described herein, the positioner assembly or positioner arms as shown may be dispensed with in some circumstances. For example, referring to **FIGS. 135 and 136**, it can be appreciated that anchor driver pins **3463** and anchors **700**, when opened within the bladder lumen and pushed downwardly until the distal ends of anchors **700** contact and possibly puncture bladder wall **2** surrounding bladder opening **4**, can be sufficient for use in capturing bladder wall **2** and pushing it downward into contact with, and securing it to, pelvic floor **7**, with bladder opening **4** and urethra opening **6** aligned, without the need for positioner

assembly **3440** as shown, in some circumstances. Thus, anchor driver assembly **3460** with anchors **700** may serve a dual function as a positioner and as an anchor driver assembly.

"H" Anchor Embodiment

[**0342**] **FIG. 83** is a perspective view of another embodiment of an anastomotic instrument **2150** of the present invention, in its pre-deployment position, and **FIG. 84** is a longitudinal cross-sectional view of the distal end of the instrument, also shown in its pre-deployment position. The instrument may comprise anchor driver assembly **2151**, which may include outer driver assembly tube **2152**, having distal end **2154**, anchor driver tube **2155** which distally terminates with anchor driver pins **2156**, and inner driver assembly tube **2158** which distally terminates with anchor track collar **2159**. The described embodiment of the instrument may further comprise positioner tube **2167**, positioner **2168** affixed to the distal end of positioner tube **2167**, rod **2170** and rod cap **2171**. When the instrument is assembled and prepared for use, anchor driver assembly **2151** may be loaded with one or more anchors **700**, each of which may comprise a forward member **750**, shaft **720** and rearward member **710**.

[**0343**] Referring to **FIG. 84** and as may be seen in more detail in **FIG. 86**, positioner tube **2167**, inner driver assembly tube **2158** distally terminating in anchor track collar **2159**, and outer driver assembly tube **2152**, may be assembled such that they are substantially coaxial. Anchor track collar **2159** and inner driver assembly tube **2158** may have in their outer surfaces one or more longitudinally-oriented anchor tracks **2160** which direct upwardly and radially outwardly, moving longitudinally, proximally to distally. Outer driver assembly tube **2152** may have one or more anchor storage grooves **2153** on its inside surface, situated opposite anchor tracks **2160**. When the instrument is assembled and ready for use, inner driver assembly tube **2158**, with anchor track collar **2159**, and outer driver assembly tube **2152**, are made integral with respect to each other by any suitable means.

[**0344**] **FIG. 87** is an enlarged view of the forward end of an anchor that may be used in the present embodiment. Anchor **700** has forward member **750** which may have a sharp forward end **751**, and has shaft **720** which connects with a rearward member **710** (not shown in **FIG. 87**). Anchor **700** may be manufactured so as to be biased with shape memory to assume an "H" shape, with the forward and rearward members forming the vertical legs and the connecting member forming the horizontal connection of the "H", and may be made of a material having suitable properties of strength, flexibility, shape memory, non-reactivity with body tissues and fluids, and biocompatibility. Anchor **700** may also be made of one or more dissolving bioabsorbable materials. Anchor **700** may, alternatively, be manufactured in a variety of suitable shapes as depicted in **FIGS. 40-51**, and one of the embodiments of the instrument described herein suitably adapted for use with such anchors substantially as hereinafter described.

[**0345**] **FIGS. 84 and 86** depict anchors **700** loaded into the instrument of the present embodiment, ready for deployment. As can be seen from the drawings, as loaded, anchors **700** reside in the spaces defined by anchor tracks **2160** and anchor storage grooves **2153**. As can be appreciated from the drawings, the spaces defined by the anchor tracks **2160** and anchor storage grooves **2153** restrain the anchors **700** while the anchors are loaded in the instrument, holding them such that forward lodging lodging members **750** and penetration limiting members **710** are positioned lying longitudinally alongside connecting members **720**.

[**0346**] As can be seen in **FIGS. 84 and 86**, when the instrument is ready for use, anchor driver pins **2156** also reside in anchor tracks **2160** with their distal ends behind the forward lodging lodging members **750** in a position ready for driving anchors **700** as will be hereinafter described. Anchor driver pins **2156** are integral with a distal end of anchor driver tube **2155** (shown in **FIG. 83**). Anchor driver tube **2155** is longitudinally movable with respect to outer driver assembly tube **2152** and inner driver assembly tube **2158**. Anchor driver pins **2156** are formed from a suitable flexible, shape memory material such as nitinol, and are biased so as to be substantially straight in their natural positions.

[**0347**] As may be seen in **FIG. 87**, the end of anchor driver pin **2156** may have a recess **2157** or any other suitable feature for receiving and holding forward member **750** during the anchor driving step as will be hereinafter described.

[**0348**] The instrument may comprise one or more anchors, and the associated tracks, grooves and anchor driver pins described above, situated about the instrument in positions such that upon correct rotational orientation of the instrument, the anchors may be driven upwardly and radially outwardly into tissues in directions selected to avoid nerve and/or circulatory system bundles or other sensitive areas.

[**0349**] Referring again to **FIG. 84**, the instrument of the present embodiment also includes positioner tube **2167**. Affixed at the distal end of positioner tube **2167** is positioner **2168**, shown in its pre-deployment shape in **FIGS. 83 and 84**. The pre-deployment shape of positioner **2168**, shown in **FIGS. 83 and 84**, facilitates insertion of the instrument into the patient. Positioner **2168** may be made of a suitable elastic and flexible polymeric material having shape memory, manufactured so as to be biased to assume a normally transversely-oriented shape such as, for example, that shown in **FIG. 89**, upon retraction of rod **2170**. As shown in **FIG. 89**, positioner **2168** may have, about its perimeter, one or more drainage holes **2169** which can permit urine, fluids or clotted material to drain into positioner tube **2167** after the instrument has been deployed. Positioner **2168** is alternately moved to its pre-deployment position shown in **FIGS. 83 and 84**, or allowed to return via shape memory to its normal (deployed) position shown in **FIG. 89**, by longitudinal movement of rod **2170**, and correspondingly, end cap **2171**, which is integrally affixed to rod **2170**. Positioner tube **2167** is longitudinally movable with respect to inner driver assembly tube **2158**, and vice versa.

[**0350**] Outer driver assembly tube **2152**, anchor driver tube **2155**, inner driver assembly tube **2158**, positioner tube **2167** and rod **2170** may be made of one or more materials having suitable combined properties of shape memory, flexibility, strength and stiffness that both enable the tubes and rod to flex during insertion into the patient's body and through the urethra as will be hereinafter described, but also

will prevent them from collapsing, kinking, binding, or breaking during use. The selected materials may also be substantially non-reactive with body fluids and tissues, and be substantially biocompatible. The inventors have determined that nitinol, known in the art as suitable for a variety of surgical devices and tubes, is one example of a suitable material.

[0351] It will be appreciated that a hollow tube may be used in the instrument for positioner tube **2167** when a coaxial arrangement with rod **2170** is desirable, or when positioner tube **2167** is to serve as a catheter, such as will be further described below, but that a rod may be substituted for positioner tube **2167** and be used to provide substantially the same mechanical function, i.e., transmission of forces to actuate the positioner, and thus may be used when a catheter function, or a coaxial arrangement, and thus a tube, is not required. Conversely, a tube can serve the purpose of rod **2170**. Thus, for purposes of claims set forth, unless otherwise specified in a claim, the term "tube" where such element is operably affixed or connected with, or contacts, the positioner, is intended to include and cover a rod, and vice versa.

[0352] A method for performing anastomosis in a retrograde manner using the above-described instrument, following a prostatectomy, will now be described. Following a prostatectomy, the patient's bladder **1** and urethra opening **6** are separated by a void formerly occupied by the prostate, as shown in **FIG. 2**. It is necessary to connect the bladder **1** with the urethra **5**, with bladder opening **4** and urethra opening **6** aligned, to restore urinary functions after recovery and healing.

[0353] As shown in **FIG. 88**, the anastomotic instrument is inserted upwardly into and through the patient's urethra **5**, through the bladder opening **4**, and into the bladder **1**. The surgeon then retracts rod **2170** and correspondingly, end cap **2171**, which allows positioner **2168** to assume its normal transversely-oriented shape via shape memory, as shown in **FIG. 89**. The now-transverse orientation of positioner **2168** prevents it from being retracted without pulling bladder wall **2** surrounding bladder opening **4** with it.

[0354] Next, the surgeon retracts the entire instrument downwardly through the urethra, which causes positioner **2168** to pull bladder walls **2** surrounding bladder opening **4** into contact with pelvic floor **7**, with bladder opening **4** and urethra opening **6** aligned, to the position shown in **FIG. 90**.

[0355] Next referring to **FIG. 91**, anchor driver tube **2155** is moved longitudinally upwardly and distally, which correspondingly causes anchor driver pins **2156** to move upwardly and distally, inside anchor tracks **2160**, and then upwardly and radially outwardly, driving forward lodging lodging members **750** of anchors **700** upwardly and radially outwardly, first into and through the tissues of the pelvic floor **7** surrounding the urethra opening **6**, and then into and through the tissues of the bladder wall **2** surrounding the bladder opening **4**, and into the bladder, as shown in **FIG. 91**. As may be seen in **FIG. 91**, as forward lodging lodging members **750** are driven into the tissues, connecting members **720** trail behind forward lodging lodging members **750**, into place in the tissues. Anchor driver tube **2155** and correspondingly anchor driver pins **2156** are then retracted back into the instrument, releasing lodging members **750** of anchors **700**. When lodging members **750** of anchors **700** are released by retraction of anchor driver pins **2156**, they are no longer restrained from their normal biased positions, and lodging members **750** move under bias and contact with the bladder wall to a position substantially transverse to the axes of connecting members **720** as may be seen in **FIG. 92**, such that lodging members **750** prevent anchors **700** from retracting back through the holes in the tissues made by lodging members **750** during the driving step, and thus, serve to lodge the anchors in the tissues. Similarly, when penetration limiting members **710** are pulled out of the instrument, they are no longer restrained from their normal biased positions, and penetration limiting members **710** move under bias and contact with the urethra wall to a position substantially transverse to the axes of connecting members **720** as may be seen in **FIG. 92**, such that penetration limiting members **710** may not be pulled through the holes in the tissues made by lodging members **750** during the driving step, and thus serve to limit further penetration of anchors **700** into the tissues. Upon completion of installation of anchors **700**, as can be seen in **FIG. 92**, anchors **700** hold the tissues of bladder wall **2** surrounding bladder opening **4** in contact with the tissues of pelvic floor **7** surrounding urethra opening **6**, with the bladder opening **4** and urethra opening **6** aligned. Thus held in contact, the tissues of the bladder wall **2** and pelvic floor **7** may knit and heal together with the bladder opening and urethra opening aligned.

[0356] Next, the entire anchor driver assembly, comprising inner driver assembly tube **2158** and anchor track collar **2159**, anchor driver tube **2155**, and outer driver assembly tube **2152**, may be retracted as a unit (as shown in progress in **FIG. 92**), down the urethra and out of the patient's body, leaving behind positioner tube **2167**, positioner **2168** and rod **2170**. Remaining positioner **2168** and positioner tube **2167** may now be used to exert supplemental downward pressure on bladder walls **2** surrounding the bladder opening **4** so as to enhance contact and knitting between the tissues of bladder walls **2** surrounding the bladder opening **4**, and the tissues of pelvic floor **7** surrounding the urethra opening **6**. Additionally, or alternatively, positioner **2168**, including drainage holes **2169**, and positioner tube **2167**, may now be used to seal off the junction between the bladder and urethra and drain urine and other fluids from the bladder during recovery and healing. Used for this purpose, positioner tube **2167** would be connected to a urine collection bag (not shown) via intermediate tubing. Following recovery and healing, rod **2170** and correspondingly end cap **2171** are moved longitudinally upwardly and distally with respect to positioner tube **2167**, thus urging positioner **2168** into its pre-deployment position as shown in **FIGS. 83 and 84**, and enabling retraction of these remaining parts of the instrument out of the bladder, down through the urethra, and out of the patient's body.

[0357] **FIGS. 93 and 94** depict an alternative embodiment and alternative loaded anchor positions for the instrument of the present invention. As can be seen, in this embodiment anchor driver pins **2156** include rear driver steps **2172**, which function to drive penetration limiting members **710** of anchors **700** at the same time the distal ends of anchor driver pins drive forward lodging lodging members **750** of anchors **700**. The geometry of outer driver assembly tube **2152**, anchor storage groove **2153** and/or anchor track **2160** are suitably modified accordingly. With this alternative embodiment, tension in shaft **720** during the driving step may be avoided and driving and ejection of the anchor from the

instrument may be eased. Additionally, as depicted in **FIG. 94**, in this alternative embodiment anchors **700** may be loaded with forward lodging lodging members **750** and penetration limiting members **710** oriented in opposite directions as shown, which may serve to improve the positioning of rearward member **710** in the urethra after actuation of the anchor driver assembly and driving of the anchors.

[**0358**] Those skilled in the art will appreciate that a variety of simple mechanical devices may be configured or adapted to operate and manipulate and outer driver assembly tube **2152** and inner driver assembly tube **2158**, anchor driver tube **2155**, positioner tube **2167** and rod **2170**, at the proximal end of the instrument as required by the above steps, and so as to move and hold the instrument in respective pre-deployment and/or retracted, and deployed and first and second actuated, positions, including but not limited to the handle assembly now to be described.

[**0359**] The right-hand side of **FIG. 83**, and **FIG. 85**, depict an example of a simple proximal end handle assembly **2200** which may be designed and configured to enable the surgeon to control and manipulate various embodiments of the instrument. Handle assembly **2200** comprises rod **2201** having affixed knob **2202**, fourth tube **2203**, third tube **2204** with integral stop collar **2205**, second tube **2207** with integral actuation collar **2209**, and first tube **2210**. Tubes **2210**, **2207**, **2204** and **2203**, and rod **2201**, may be substantially coaxial. Rod **2201** is longitudinally slidable with respect to fourth tube **2203**. Fourth tube **2203** is longitudinally slidable with respect to third tube **2204** and stop collar **2205**, and vice versa. First tube **2210** may be connected to third tube **2204** via connecting pins **2211**, thus making first tube **2210** and third tube **2204** integral. Second tube **2207** is coaxially located between first tube **2210** and third tube **2204**, and is longitudinally slidable therewithin, to the limits defined by longitudinal slots **2208** in second tube **2207** about pins **2211**.

[**0360**] Thus, it can be appreciated from **FIGS. 84 and 85** that handle assembly **2200** may be connected and made usable by the surgeon to manipulate and operate anastomotic instrument **2150** by connecting, or making integral, rod **2201** and rod **2170**, fourth tube **2203** and positioner tube **2167**, third tube **2204** and inner driver assembly tube **2158**, second tube **2207** and anchor driver tube **2155**, and first tube **2210** and outer driver assembly tube **2152**. As so configured, second tube **2207** may be longitudinally slid with respect to the remaining parts of the assembly by the surgeon gripping tube actuation collar **2209**, thus advancing or retracting anchor driver tube **2155** and correspondingly anchor driver pins **2156**, thereby actuating anchor driver assembly **2151**. Following installation of the anchors, the entire anchor driver assembly **2151** may be retracted from the patient's body by the surgeon gripping and pulling first tube **2210**, thus also retracting third tube **2204** via connecting pins **2211** and second tube **2207**, and correspondingly, retracting outer anchor driver assembly tube **2152**, inner driver assembly tube **2158**, and anchor driver tube **2155**. This can be accomplished while leaving behind fourth tube **2203** and rod **2201**, and thus positioner tube **2167** and rod **2170**, as described above.

[**0361**] It will be appreciated by those skilled in the art of design of mechanical surgical devices that the positioner need not be limited to the exemplary embodiment made of flexible and elastic polymeric shape memory material as described above, but that alternative designs for such positioner are possible, which cause the positioner to alternately assume a retracted position and a deployed position, the deployed position suitable for catching in the bladder opening and urging the bladder into contact with the pelvic floor, in response to forces exerted or transmitted by tubes or other members. The positioner may comprise, for example, any of the positioner assemblies depicted in **FIGS. 14, 19, 24** and **57**, and described hereinabove. Similarly, it will be appreciated by those skilled in the art of design of mechanical surgical devices that the anchor driver assembly need not be limited to the exemplary three-tube assembly described herein, but that alternative designs for such an assembly are possible, which are effective to install one or more anchors into the tissues of the bladder and the urethra about the respective openings when they are brought together, in response to forces exerted or transmitted by tubes or other members.

[**0362**] As previously noted, the combination of tubes, positioner and driver assembly may be configured in an instrument adapted for a retrograde anastomosis procedure, as described above, or configured in an instrument adapted for an antegrade procedure. In an antegrade procedure, instead of being inserted upwardly through the urethra and into the bladder opening proximate the site of excision of the prostate, the instrument is inserted downwardly through a small incision in the patient's abdomen, through a small incision on an upper surface of the patient's bladder, into the bladder, through the bladder opening, and into the urethra opening. The small incisions in the abdomen and upper surface of the bladder may be made and held open for insertion of the instrument therethrough with a cannula and trocar assembly.

Connecting Anchor Embodiment

[**0363**] **FIG. 95** is a perspective view of another embodiment of an anastomotic instrument **2100** of the present invention, in its pre-deployment position, and **FIG. 96** is a longitudinal cross-sectional view of the distal end of the instrument, also shown in its pre-deployment position. The instrument may comprise anchor driver assembly **2101**, which may include outer driver assembly tube **2102**, having distal end **2104**, second anchor track collar **2105**, anchor driver tube **2109** which distally terminates with anchor driver pins **2108**, and inner driver assembly tube **2110** which distally terminates with first anchor track collar **2112**. The present embodiment may further comprise positioner tube **2121**, positioner **2122** affixed to the distal end of positioner tube **2121**, rod **2124** and rod cap **2125**. When the instrument is assembled and prepared for use, anchor driver assembly **2101** may be loaded with one or more anchor pairs, each pair comprising first anchor **700** with an attached length of suture **2117**, and second anchor **701**.

[**0364**] Referring to **FIG. 96** and as may be seen in more detail in **FIGS. 97 and 98**, positioner tube **2121**, inner driver assembly tube **2110** distally terminating in first anchor track collar **2112**, second anchor track collar **2105**, and outer driver assembly tube **2102**, may be assembled such that they are substantially coaxial, with first anchor tracks **2111**, second anchor tracks **2106** and anchor driver pins **2108** longitudinally aligned. First anchor track collar **2112** may have in its outer surface one or more longitudinally-oriented

first anchor tracks **2111** including suture clearance tracks **2113**, which direct upwardly and radially outwardly, moving longitudinally, proximally to distally. Second anchor track collar **2105** may have in its outer surface one or more longitudinally-oriented second anchor tracks **2106**, which also direct upwardly and radially outwardly, moving longitudinally, proximally to distally. Second anchor track collar **2105** also has suture clearance tracks **2107** on its inside surface, situated opposite suture clearance tracks **2113** in first anchor track collar **2112**, and one or more longitudinally-oriented suture storage grooves **2103** on its outer surface. Distal end **2104** of outer driver assembly tube **2102** may have on its outer surface one or more longitudinally-oriented suture storage grooves **2103**, that align with and thereby form extensions of suture storage grooves **2103** on second anchor track collar **2105**. When the instrument is assembled and ready for use, inner driver assembly tube **2110**, with first anchor track collar **2112**, second anchor track collar **2105**, and outer driver assembly tube **2102**, may be made integral with respect to each other by any suitable means.

[**0365**] **FIGS. 99-101** are enlarged views of exemplary anchors that may be used in the present embodiment. First anchor **700** may have barb **730** and suture holes **735**. Suture holes **735** may be used to attach a length of trailing suture or other suitable connecting member to first anchor **700** in preparation for use. Second anchor **701** may have barb **731** and suture notch **752**. Suture notch **752** is shaped and sized so as to be effective to capture and bindingly hold a free end of suture or other suitable connecting member as will be hereinafter described. Anchors **700** and **701** may be manufactured so as to be biased to assume the shapes shown in **FIGS. 99-101**, and may be made of a material having suitable properties of strength, flexibility, shape memory, non-reactivity with body tissues and fluids, and biocompatibility. Anchors **700** and **701** may also be made of dissolving bioabsorbable materials, or may be made of suitably treated nitinol or surgical stainless steel.

[**0366**] **FIGS. 96-98** depict first anchors **700** and second anchors **701** loaded into the present embodiment of an anastomotic instrument, ready for deployment. As can be seen from the drawings, as loaded, first anchors **700** may reside in the spaces defined by first anchor tracks **2111** and the interior surface of second anchor track collar **2105**. Similarly, second anchors **701** may reside in the spaces defined by second anchor tracks **2106** and the interior surface of outer driver assembly tube **2102**. As can be appreciated from the drawings, the spaces defined by the anchor tracks **2111** and **2106** restrain the barbs **730** and **731** of anchors **700** and **701** while the anchors are loaded in the instrument. Sutures **2117** or other suitable connecting members may be attached to the rear ends of first anchors **700** via suture holes **735** (shown in **FIG. 99**) and trail from the rear ends of first anchors **700**, upwardly through suture clearance tracks **2107**, radially out and over second anchor track collar **2105**, and downwardly in suture storage grooves **2103**, terminating with free ends.

[**0367**] As can be seen in **FIGS. 96-98**, when the instrument is ready for use anchor driver pins **2108** reside in first anchor tracks **2111** with their distal ends behind anchors **700** in preparation for driving first anchors **700** as will be hereinafter described. Anchor driver pins **2108** are integral with a distal end of anchor driver tube **2109** (shown in **FIG. 95**). Anchor driver tube **2109** is longitudinally movable with respect to outer driver assembly tube **2102** and inner driver assembly tube **2110**. Anchor driver pins **2108** are made of a suitable flexible, shape memory material such as nitinol, and are biased so as to have their distal ends spring radially outwardly upon repositioning in preparation for driving second anchors **701**, as will be described below.

[**0368**] The instrument may comprise one or more pairs of anchors, each pair comprising a first anchor and a second anchor, and the associated tracks, grooves and anchor driver pins described above, situated radially about the instrument in positions such upon correct rotational orientation of the instrument, the anchors may be driven into tissues in directions selected to avoid nerve and/or circulatory system bundles or other sensitive areas.

[**0369**] Referring again to **FIG. 96**, the instrument of the present embodiment also may include positioner tube **2121**. Affixed at the distal end of positioner tube **2121** is positioner **2122**, shown in its pre-deployment shape in **FIGS. 95 and 96**. The pre-deployment shape of positioner **2122**, shown in **FIGS. 95 and 96**, can facilitate insertion of the instrument into the patient. Positioner **2122** may be made of a suitable elastic and flexible polymeric material having shape memory, manufactured so as to be biased to assume a normally transversely-oriented shape as shown in **FIG. 103**, upon retraction of rod **2124**. As shown in **FIG. 103**, positioner **2122** may have, about its perimeter, one or more drainage holes **2123** that can permit urine, fluids or clotted material to drain into positioner tube **2121** after the instrument has been deployed. Positioner **2122** may be, alternately, moved to a pre-deployment position shown in **FIGS. 95 and 96**, or allowed to return via shape memory to a normal (deployed) position shown in **FIG. 103**, by longitudinal movement of rod **2124**, and correspondingly, end cap **2125**, which may be integrally affixed to rod **2124**. Positioner tube **2121** is longitudinally movable with respect to inner driver assembly tube **2110**, and vice versa.

[**0370**] Outer driver assembly tube **2102**, anchor driver tube **2109**, inner driver assembly tube **2110**, positioner tube **2121** and rod **2124** may be made of a material having suitable combined properties of shape memory, flexibility, strength and stiffness that both enable the tubes and rod to flex during insertion into the patient's body and through the urethra as will be described below, but also will prevent them from collapsing, kinking, binding, or breaking during use. The selected material may also be substantially non-reactive with body fluids and tissues, and be substantially biocompatible, or be non-biocompatible with a biocompatible coating. The inventors have determined that nitinol, known in the art as suitable for a variety of surgical devices and tubes, is one example of a suitable material.

[**0371**] It will be appreciated that hollow tubes may be used in the instrument for positioner tube **2121** when a coaxial arrangement with rod **2124** is desirable, or when positioner tube **2121** is to serve as a catheter, such as will be further described below, but that a rod may be substituted for positioner tube **2121** and be used to provide substantially the same mechanical function, i.e., transmission of forces to actuate the positioner, and thus may be used when a catheter function, or a coaxial arrangement, and thus a tube, is not required. Conversely, a tube can serve the purpose of rod **2124**. Thus, for purposes of the claims set forth herein,

unless otherwise specified in a claim, the term "tube" where such element is operably affixed or connected with, or contacts, the positioner, is intended to include and cover a rod, and vice versa.

[0372] A method for performing anastomosis of a patient's bladder and urethra using the above-described anastomotic instrument, following a prostatectomy, will now be described. Following a prostatectomy, the patient's bladder **1** and urethra opening **6** are separated by a void formerly occupied by the prostate, as shown in **FIG. 2**. It is necessary to connect the bladder **1** with the urethra **5**, with bladder opening **4** and urethra opening **6** aligned, to restore urinary functions after recovery and healing.

[0373] As shown in **FIG. 102**, the anastomotic instrument may be inserted upwardly into and through the patient's urethra **5**, through the bladder opening **4**, and into the bladder **1**. The surgeon then may retract rod **2124** and correspondingly, end cap **2125**, which will permit positioner **2122** to assume its normal shape via shape memory, as shown in **FIG. 103**. The now-transverse orientation of positioner **2122** will prevent it from being retracted without pulling bladder wall **2** surrounding bladder opening **4** with it.

[0374] Next, the surgeon may retract the entire instrument downwardly through the urethra, which will cause positioner **2122** to pull bladder walls **2** surrounding bladder opening **4** into contact with pelvic floor **7**, with bladder opening **4** and urethra opening **6** aligned, to the position shown in **FIG. 104**.

[0375] Next referring to **FIG. 105**, anchor driver tube **2109** may be moved longitudinally distally, which correspondingly will cause anchor driver pins **2108** to move upwardly and distally inside first anchor tracks **2111**, driving first anchors **700** radially outwardly into the surrounding tissues of bladder wall **2**, as shown in **FIG. 105**. When anchors **700** are driven out of the instrument, they are no longer restrained from their normal biased shapes, and thus barbs **730** can spring away from anchors **700** as shown, enabling anchors **700** to lodge in the tissues. After anchors **700** are driven into the bladder wall tissues, the attached sutures **2117** will trail from the rear ends of anchors **700**, back out of the tissues, with their free ends continuing to reside in suture storage grooves **2103**, passing over the exits of second anchor tracks **2106**.

[0376] Next, referring to **FIG. 106**, anchor driver tube **2109** and correspondingly, anchor driver pins **2108**, may be longitudinally retracted proximally. When the distal ends of anchor driver pins **2108** are retracted past the proximal end of second anchor track collar **2105**, the shape-memory bias of anchor driver pins **2108** will cause their distal ends to move radially outwardly into position behind second anchors **701**, into the position shown in **FIG. 106**, ready to drive second anchors **701** upwardly and outwardly through second anchor tracks **2106**.

[0377] Next, referring to **FIG. 107**, anchor driver tube **2109** and correspondingly anchor driver pins **2108** may again be pushed longitudinally distally, while will cause the distal ends of anchor driver pins **2108** move distally into and through second anchor tracks **2106**, and drive second anchors **701** radially outwardly into the surrounding tissues of pelvic floor **7**, as shown in **FIG. 107**. As the fore ends of second anchors **701** are driven out of the instrument, suture notches **752** (see **FIG. 100**) will contact the trailing lengths of sutures **2117** passing over the exits of second anchor tracks **2106** (see **FIG. 106**), and capture and bindingly hold these trailing lengths as second anchors **701** are driven into the tissues, as shown in **FIG. 107**. Thus, for each installed pair of anchors comprising first and second anchors **700** and **701**, a suture **2117** (or other suitable connecting member) may be anchored into a position holding the tissues of bladder wall **2** surrounding bladder opening **4** in contact with the tissues of pelvic floor **7** surrounding urethra opening **6**, with the bladder opening **4** and urethra opening **6** aligned. Thus held in contact, the tissues of the bladder wall **2** and pelvic floor **7** may knit and heal together and the bladder opening and urethra opening aligned.

[0378] Next, the entire anchor driver assembly, comprising inner driver assembly tube **2110** and first anchor track collar **2112**, anchor driver tube **2109**, second anchor track collar **2105**, and outer driver assembly tube **2102**, may be retracted as a unit (as shown in progress in **FIG. 108**), down the urethra and out of the patient's body, leaving behind positioner tube **2121**, positioner **2122** and rod **2124**. Remaining positioner **2122** and positioner tube **2121** may now be used to exert supplemental downward pressure on bladder walls **2** surrounding the bladder opening **4** so as to enhance contact and knitting between the tissues of bladder walls **2** surrounding the bladder opening **4**, and the tissues of pelvic floor **7** surrounding the urethra opening **6**. Additionally, or alternatively, positioner **2122**, including drainage holes **2123**, and positioner tube **2121**, may now be used to seal off the junction between the bladder and urethra and drain urine, fluids and/or clotted material from the bladder during recovery and healing. Used for this purpose, positioner tube **2121** would be connected to a urine collection bag (not shown) via intermediate tubing. Following recovery and healing, rod **2124** and correspondingly end cap **2125** may be moved longitudinally upwardly or distally with respect to positioner tube **2121**, thus urging positioner **2122** into its pre-deployment position as shown in **FIG. 109**, and enabling retraction of these remaining parts of the instrument out of the bladder, down through the urethra, and out of the patient's body.

[0379] Those skilled in the art of the design of mechanical surgical devices will appreciate that a variety of simple mechanical devices may be configured or adapted to actuate and manipulate outer driver assembly tube **2102** and inner driver assembly tube **2110**, anchor driver tube **2109**, positioner tube **2121** and rod **2124**, at the proximal end of the instrument as required by the above steps, and so as to move and hold the instrument in respective pre-deployment and/or retracted, and deployed and first and second actuated, positions, including the handle assembly depicted in **FIGS. 83 and 85** and described above, or a variation thereof.

[0380] It will be appreciated by those skilled in the art of design of mechanical surgical devices that the positioner need not be limited to the embodiment made of flexible and elastic polymeric shape memory material as described herein, but that alternative designs for such positioner are possible, which can cause the positioner to alternately assume a retracted position and a deployed position, the deployed position suitable for catching in the bladder opening and urging the bladder into contact with the pelvic floor, in response to forces exerted or transmitted by tubes or other

members. The positioner may comprise, for example, any of the positioner assemblies depicted in **FIGS. 14, 19, 24** and **57**, and described hereinabove. Similarly, it will be appreciated by those skilled in the art of design of mechanical surgical devices that the anchor driver assembly need not be limited to the three-tube assembly described herein, but that alternative designs for such an assembly are possible, which cause the anchor driver assembly to install one or more connected pairs of anchors into the tissues of the bladder and the urethra radially about the respective openings of these lumens when they are brought together, in response to forces exerted or transmitted by tubes or other members.

[**0381**] As previously noted, the combination of tubes, positioner and driver assembly may be designed and configured in an instrument adapted for a retrograde anastomosis procedure, as described above, or configured in an instrument adapted for an antegrade procedure. In an antegrade procedure, instead of being inserted upwardly through the urethra and into the bladder opening proximate the site of excision of the prostate, the instrument is inserted downwardly through a small incision in the patient's abdomen, through a small incision on an upper surface of the patient's bladder, into the bladder, through the bladder opening, and into the urethra opening. The small incisions in the abdomen and upper surface of the bladder may be made with a cannula and trocar assembly and held open by the cannula for insertion of the instrument therethrough.

Deformable Fastener Embodiment

[**0382**] **FIG. 110** is a perspective view of another embodiment of an anastomotic instrument **2050** of the present invention, in its pre-deployment position, and **FIG. 111** is a longitudinal cross-sectional view of the instrument, also shown in its pre-deployment position, after insertion into and through the patient's urethra and into the bladder **1**. The instrument may comprise fastener driver assembly **2052** including outer tube **2051** and second tube **2060**. Outer tube **2051** may terminate with flexible fingers **2053**, which in turn terminate with proximal fastener anvils **2054**. Second tube **2060** may be immediately inside and substantially coaxial with outer tube **2051**. Second tube **2060** may terminate with flexible fingers **2061**, which in turn terminate with distal fastener anvils **2062**, which may be longitudinally aligned with and may longitudinally oppose proximal fastener anvils **2054**.

[**0383**] When the fastener driver assembly **2052** is being assembled in preparation for its use, fastener set **2070** in its pre-deployment shape (shown in enlarged perspective view in **FIG. 119**) is placed onto second tube **2060** and moved over flexible fingers **2061** to a position in which the upper prongs of fasteners **2072** of fastener set **2070** are proximate to upper anvils **2062**. Next, outer tube **2051** may be slid over and up second tube **2060**, until lower anvils **2054** are in a position proximate to the lower prongs of fasteners **2072** of fastener set **2070**, thus holding fastener set **2070** in a position on the fastener driver assembly ready for deployment (as shown in **FIG. 110**) via actuation of the fastener driver assembly as will be described below.

[**0384**] Thus, it can be seen in **FIGS. 110 and 111** that fastener driver assembly **2052** may comprise outer tube **2051** with its flexible fingers **2053** and lower anvils **2054**, second tube **2060**, with its flexible fingers **2061** and upper anvils **2062**. When fastener assembly **2052** is assembled and made ready for use, it may include fastener set **2070** in a pre-deployment shape, placed as shown.

[**0385**] **FIG. 119** shows an exemplary fastener set **2070** in a pre-deployment shape. One or more individual fasteners **2072** may have upper and lower prongs with ends turned slightly outwardly, and may be linked together via serpentine links **2071**. **FIG. 120** shows fastener set **2070** as it would appear following installation. In its installed shape, fastener set **2070** has been expanded in circumference and diameter via deformation of serpentine links **2071**, and fasteners **2072** have been pushed and deformed so as to hook into tissues. Fastener set **2070** may be made of a suitable substantially permanently deformable material that is non-reactive with body fluids and tissues, and substantially biocompatible. The inventors have determined that suitably treated surgical stainless steel is one example of a suitable material. Alternatively, if it is desired that the fastener set be bioabsorbable, a suitably deformable substantially biocompatible and bioabsorbable material may be selected. The inventors have determined that flexible absorbable polymers (e.g., polydioxanone polymers, or polymers containing lactides, glycolides, polyglactin, etc., such as the polymers marketed by Johnson & Johnson and/or Ethicon, Inc. under the trademarks "Vicryl" and "PDS II") such that the fastener set can be absorbed (i.e., dissolved) in the patient's body after anastomosis is complete. If the selected material is one that might not sufficiently retain its position after deformation during installation, the design of the fastener set may be modified so as to include barbs on the prongs or other suitable lodging structures, or include features that cause the prongs to meet and interlock upon installation, to form substantially closed rings.

[**0386**] Referring back to **FIGS. 110 and 111**, the instrument of the present embodiment may also include third tube **2080**, which may terminate with expander collar **2081**. Affixed at the distal end of expander collar **2081** is positioner **2090**, shown in a pre-deployment shape in **FIGS. 110 and 111**.

[**0387**] The pre-deployment shape of positioner **2090**, shown in **FIGS. 110 and 111**, can facilitate insertion of the instrument into the patient. Positioner **2090** may be made of a suitable elastic and flexible polymeric material having shape memory, manufactured so as to be biased to assume a normally transversely oriented shape as shown in **FIG. 112**, upon retraction of actuator rod **2092**. As shown in **FIG. 112**, positioner **2090** may have situated thereabout one or more drainage holes **2091** which can permit urine, fluids or clotted material to drain into third tube **2080** after the instrument has been deployed. Positioner **2090** may be, alternately, moved to a pre-deployment position shown in **FIGS. 110 and 111**, or allowed to return via shape memory to a normal position shown in **FIG. 112**, by longitudinal movement of rod **2092**, and correspondingly, end cap **2093**, which may be integrally affixed to rod **2092**.

[**0388**] As shown in **FIG. 121**, end cap **2093** may have thereabout one or more flutes **2094** which can serve to allow urine or other fluids draining out of the bladder, through drainage holes **2091** in positioner **2090**, past end cap **2093** and down into third tube **2080**, by which they can be drained out of the patient.

[**0389**] Outer tube **2051**, second tube **2060**, third tube **2080** and rod **2092** may be made of a material having suitable

combined properties of shape memory, flexibility, strength and stiffness that both enable the tubes and rod to flex during insertion into the patient's body and through the urethra as will be hereinafter described, but also will prevent them from collapsing, kinking, binding, or breaking during use. The selected material may also be substantially non-reactive with body fluids and tissues, and be substantially biocompatible. The inventors have determined that nitinol, known in the art as suitable for a variety of surgical devices and tubes, is one example of a suitable material.

[0390] It will be appreciated that hollow tubes may be used in the instrument for third tube **2080** when a coaxial arrangement with rod **2092** is desirable, or when third tube **2080** is to serve as a catheter, such as will be further described below, but that a rod may be substituted for third tube **2080** and be used to provide substantially the same mechanical function, i.e., transmission of forces to actuate the positioner, and thus may be used when a catheter function, or a coaxial arrangement, and thus a tube, is not required. Conversely, a tube can serve the purpose of rod **2092**. Thus, for purposes of the claims that may be set forth, unless otherwise specified in a claim, the term "tube" where such element is operably affixed or connected with, or contacts, the positioner, is intended to include and cover a rod, and vice versa.

[0391] Referring to **FIG. 110**, the instrument **2050** may also comprise a movable, removable, or releasable, collar or sleeve (not shown) sheathing fastener driver assembly **2052** and/or the space between expander collar **2081** and fastener driver assembly **2052**, so as to give the instrument a smoother longitudinal cross-sectional profile, to ease insertion and/or retraction of the instrument from a patient.

[0392] A method for performing anastomosis of a patient's bladder and urethra using the above-described anastomotic instrument, following a prostatectomy, will now be described. Following a prostatectomy, the patient's bladder **1** and urethra opening **6** are separated by a void formerly occupied by the prostate, as shown in **FIG. 2**. It is necessary to connect the bladder **1** with the urethra **5**, with bladder opening **4** and urethra opening **6** aligned, to restore urinary functions after recovery and healing.

[0393] As shown in **FIG. 111**, the anastomotic instrument may be inserted upwardly into and through the patient's urethra **5**, through the bladder opening **4**, and into the bladder **1**. The surgeon then may proximally retract rod **2092** and correspondingly, end cap **2093**, which allows positioner **2090** to assume its normal shape via shape memory, as shown in **FIG. 112**. The now-transverse orientation of positioner **2090** will prevent it from being retracted without pulling bladder wall **2** surrounding bladder opening **4** with it.

[0394] Next, the surgeon may proximally retract third tube **2080**, and correspondingly, expander collar **2081**, drawing expander collar **2081** inside and between distal fastener anvils **2062**, to the position shown in **FIG. 113**. Drawing expander collar **2081** inside and between distal fastener anvils **2062** will urge distal fastener anvils **2062**, and correspondingly, flexible fingers **2061** (shown in **FIG. 110**) radially outwardly as indicated in **FIG. 113**. This movement of flexible fingers **2061** radially outwardly forces fastener set **2070**, residing on and around flexible fingers **2061** below distal fastener anvils **2062**, to expand in diameter and circumference, via deformation of serpentine links **2071** (shown in detail in **FIG. 119**).

[0395] Next, the surgeon may retract the entire instrument downwardly through the urethra, which will cause positioner **2090** to pull bladder walls **2** surrounding bladder opening **4** into contact with pelvic floor **7**, with bladder opening **4** and urethra opening **6** aligned, to the position shown in **FIG. 114**.

[0396] Next, outer tube **2051** may be moved distally, while second tube **2060** and the remaining portions of the instrument are held immobile. As can be appreciated from **FIGS. 115 and 116**, this movement correspondingly moves proximal fastener anvils **2054** toward distal fastener anvils **2062**, such that they opposingly contact, urge and deform upper and lower prongs of fasteners **2072** of fastener set **2070** such that they are pushed into the surrounding tissues of the bladder wall and pelvic floor, such that they form substantially opposing, joined hooks in the respective tissues, or even, possibly, ring shapes (see also **FIG. 120**). The fasteners, thus installed, can serve to secure the tissues of the bladder wall **2** to the tissues of the pelvic floor **7**, proximate the openings of the bladder and urethra, with these openings aligned.

[0397] Next, the surgeon may move outer tube **2051** proximally while holding second tube **2060** immobile, causing proximal fastener anvils **2054** and distal fastener anvils **2062** to release their grip on fasteners **2072** and move apart, to the position shown in **FIG. 117**. The surgeon then may move third tube **2080** and correspondingly, expander collar **2081**, distally while holding second tube **2060** immobile, pushing expander collar **2081** distally out from between upper anvils **2062** and flexible fingers **2061**, permitting flexible fingers **2061** and upper anvils **2062** to return to their pre-deployment positions, circumscribing a circle of a diameter smaller than that of the now-enlarged, deployed fastener set, so as to permit retraction of the fastener driver assembly therethrough.

[0398] Next, entire fastener driver assembly **2052**, comprising outer tube **2051**, flexible fingers **2053**, proximal fastener anvils **2054**, second tube **2060**, flexible fingers **2061** and distal fastener anvils **2062**, may be retracted from the patient, leaving behind third tube **2080**, expander collar **2081**, positioner **2090**, rod **2092** and end cap **2093** as shown in **FIG. 118**. Remaining positioner **2090** and third tube **2080** may now be used to exert supplemental downward pressure on bladder walls **2** surrounding the bladder opening so as to enhance contact and knitting between the tissues of bladder walls **2** surrounding the bladder opening, and the tissues of pelvic floor **7** surrounding the urethra opening. Additionally, or alternatively, positioner **2090**, including drainage holes **2091**, and third tube **2080** may now be used to seal off the junction between the bladder and urethra and drain urine, fluids and/or clotted material from the bladder during recovery and healing. Fluids are permitted to flow past end cap **2093** via flutes **2094** in end cap **2093**, shown in **FIG. 121**. Used for this purpose, third tube **2080** would be connected to a urine collection bag (not shown) via intermediate tubing. Following recovery and healing, rod **2092** and correspondingly end cap **2093** are moved distally with respect to third tube **2080**, thus urging positioner **2090** into its pre-deployment position shown in **FIGS. 110 and 111**,

and enabling retraction of these remaining parts of the instrument out of the bladder, down through the urethra, and out of the patient's body.

[0399] Those skilled in the art of the design of mechanical surgical devices will appreciate that a variety of simple mechanical devices may be configured or adapted to operate and hold outer tube **2051**, second tube **2060**, third tube **2080** and rod **2092**, at the proximal end of the instrument as required by the above steps, and so as to move and hold the instrument in respective pre-deployment and/or retracted, and deployed and actuated, positions, including the handle assembly depicted in **FIGS. 83 and 85** and described above, or a variation thereof.

[0400] It will be appreciated by those skilled in the art of design of mechanical surgical devices that the positioner need not be limited to the embodiment made of flexible and elastic polymeric shape memory material as described immediately above, but that alternative designs for such positioner are possible, which cause the positioner to assume, alternately, a retracted position and a deployed position, the deployed position suitable for catching in the bladder opening and urging the bladder into contact with the pelvic floor, in response to forces exerted or transmitted by tubes or other members. The positioner may comprise, for example, any of the positioner assemblies depicted in **FIGS. 14, 19, 24** and **57**, and described above. Similarly, it will be appreciated by those skilled in the art of design of mechanical surgical devices that the fastener driver assembly need not be limited to the two-tube assembly described herein, but that alternative designs for such an assembly are possible, which can cause the fastener driver assembly to install one or more fasteners in the tissues of the bladder and the urethra about the respective openings of these lumens when they are brought together, in response to forces exerted or transmitted by tubes or other members.

[0401] As previously noted, the combination of tubes, positioner and driver assembly may be configured in an instrument adapted for a retrograde anastomosis procedure, as described above, or configured in an instrument adapted for an antegrade procedure. In an antegrade procedure, instead of being inserted upwardly through the urethra, and into the bladder opening proximate the site of excision of the prostate, the instrument is inserted downwardly through a small incision in the patient's abdomen, through a small incision on an upper surface of the patient's bladder, into the bladder, through the bladder opening, and into the urethra opening. The small incisions in the abdomen and upper surface of the bladder may be made with a cannula and trocar assembly and held open by the cannula for insertion of the instrument therethrough.

Lodging Member Embodiment

[0402] **FIG. 122** illustrates in longitudinal cross-section another embodiment of an anastomotic instrument **2010** of the present invention, in its pre-deployment position. The instrument may comprise inner tube **2011**, outer tube **2012** and rod **2019**, which may be of sizes such that inner tube **2011** can be placed and be movable within outer tube **2012**, and rod **2019** can be placed and be movable within inner tube **2011**, in an approximately coaxial arrangement. Inner tube **2011**, outer tube **2012** and rod **2019** may be made of a material having suitable combined properties of shape memory, flexibility, strength and stiffness that both enable the tubes to flex during insertion into the patient's body and through the urethra as will be hereinafter described, but also will prevent them from collapsing, kinking, binding, or breaking during use. The selected material may also be substantially non-reactive with body fluids and tissues, and be substantially biocompatible. The inventors have determined that nitinol, known in the art as suitable for a variety of surgical devices and tubes, is an example of suitable material.

[0403] As shown in **FIG. 122**, instrument **2010** comprises positioner **2017**. In its pre-deployment position positioner **2017** may be substantially cylindrical, having a radius smaller or approximately equal to the radius of first tube **2012**, and may have a rounded distal end. The pre-deployment shape of positioner **2017** will facilitate insertion of the instrument into the patient. Positioner **2017** may be made of a suitable elastic and flexible polymeric material having shape memory, manufactured so as to be biased to assume a normally transversely-oriented shape as shown in **FIG. 124**, upon retraction of rod **2019**. As shown in **FIG. 124**, positioner **2017** may have, about its perimeter, one or more drainage holes **2018** which can permit urine, fluids or clotted material to drain into inner tube **2011** when the instrument is deployed.

[0404] Instrument **2010** may also comprise lodging member **2013**. Lodging member **2013** also may be a tube-like member, with a proximal end **2015** affixed to the distal end of outer tube **2012**, and a distal end **2014** affixed to the distal end of inner tube **2011**. In the present embodiment lodging member **2013** is operable upon deployment to present transversely-extending ribs or other projections that enable it, upon appropriate placement and longitudinal compression, to lodge within the patient's urethra. As shown in **FIG. 126**, lodging member **2013** may have a series of circumferential, pre-formed folds **2016**, which enable lodging member **2013** to longitudinally compress when outer tube **2012** is pushed in a distal direction while inner tube **2011** is held immobile. Thus, upon longitudinal compression, lodging member **2013** can fold in accordion-like fashion to present transversely-extending ribs or other projections that when in position within the patient's urethra, can serve to lodge the instrument in place. Lodging member **2013** may be formed of polyurethane but may also be formed of any other suitable material.

[0405] Referring again to **FIG. 122**, rod **2019** is capped with end cap **2020**, which may be rounded and adapted to spread the force exerted by rod **2019** against the inside of positioner **2017** so as to prevent rod **2019** from puncturing positioner **2017**. Referring to **FIG. 127**, end cap **2020** may have thereabout one or more flutes **2021** which can allow urine, fluids or clotted material to flow past end cap **2020** when rod **2019** is retracted. As affixed to rod **2019**, end cap **2020** is substantially integral therewith.

[0406] It will be appreciated that hollow tubes may be used in the instrument for inner tube **2011** and outer tube **2012** when a coaxial arrangement is desirable, or when one or more of these members is to serve as a catheter, such as will be further described below, but that one or more rods may be substituted for tubes and be used to provide substantially the same mechanical functions, i.e., transmission of forces to actuate the positioner and the lodging member,

and thus, may be used when a catheter function, or a coaxial arrangement, and thus a tube, is not required. Thus, for purposes of the claims that may be set forth, unless otherwise specified in a claim, the term "tube" is intended to include and cover a rod.

[0407] A method for performing anastomosis of a patient's bladder and urethra, using the above-described retrograde anastomotic instrument, following a prostatectomy, will now be described. Following a prostatectomy, the patient's bladder **1** and urethra opening **6** are separated by a void formerly occupied by the prostate, as shown in **FIG. 2**. It is necessary to connect the bladder **1** with the urethra **5**, with bladder opening **4** and urethra opening **6** aligned, to restore urinary functions after recovery and healing.

[0408] As shown in **FIG. 123**, anastomotic instrument **2010** maybe inserted upwardly into and through the patient's urethra **5** (as can be appreciated from **FIG. 127**), through the bladder opening **4**, and into the bladder **1**. The surgeon may then proximally retract rod **2019** with attached end cap **2020**, which will allow positioner **2017** to assume its normal shape, which extends transversely to the longitudinal axis of the instrument within the bladder, beyond the diameter of the bladder opening **4**, as shown in **FIG. 124**. The now-transverse orientation of positioner **2017** prevents it from being retracted without pulling bladder wall **2** surrounding bladder opening **4** with it.

[0409] Next, the surgeon may retract the entire instrument downwardly through the urethra, which causes positioner **2017** to pull bladder walls **2** surrounding bladder opening **4** into contact with pelvic floor **7**, with bladder opening **4** and urethra opening **6** aligned, in the position shown in **FIG. 125**.

[0410] Next, outer tube **2012** may be moved distally, while inner tube **2011** is held immobile. As can be appreciated from **FIG. 126**, because the proximal end of lodging member **2013** is affixed to the distal end of outer tube **2012** at point A, and the distal end of lodging member **2013** is affixed to the distal end of inner tube **2011** at point B as shown, this distal movement of outer tube **2012** relative to immobile inner tube **2011** will cause longitudinal compression of lodging member **2013**. Pre-formed circumferential folds **2016** in lodging member **2013** cause lodging member **2013** to compress in accordion-like fashion, resulting in the presentation of transversely-extending ribs as shown, which enable the lodging member **2013**, and consequently, the entire instrument, to lodge in the urethra in the position shown in **FIG. 126**.

[0411] As shown by way of example but not of limitation in **FIGS. 131-133**, lodging member **2013** may be configured in various embodiments as shown, such as including perforations which can serve to alleviate radial stresses in the material and thereby facilitate deployment, and also cause lodging member **2013** to present transversely-extending projections **2042**, when longitudinally compressed, enhancing its effectiveness in lodging within the urethra. Lodging member **2013** may also be manufactured so as to have a rough outer surface, which can also serve to enhance its effectiveness in lodging within the urethra. It may be desirable to design the lodging member so that any lodging projections that enhance its effectiveness in lodging within the urethra are limited in length so as not to substantially pierce or penetrate surrounding tissues, so as to minimize the possibility of causing permanent damage to sensitive areas in the tissues.

[0412] Those skilled in the art of the design of mechanical surgical devices will appreciate that a variety of simple mechanical devices may be configured or adapted to operate and hold inner tube **2011**, outer tube **2012** and rod **2019** at the proximal end of the instrument as required by the above steps, and so as to move and hold the instrument in respective retracted, and then deployed and lodged, positions, including the handle assembly depicted in **FIGS. 83 and 85** and described above, or a variation thereof.

[0413] In the lodged position shown in **FIG. 126**, the instrument may be used to hold the bladder wall **2** surrounding the bladder opening **4** in contact with the pelvic floor **7** surrounding the urethra opening **6** with bladder opening **4** and urethra opening **6** aligned, during the period of time necessary for these tissues to knit and heal together naturally.

[0414] While the instrument is lodged in position shown in **FIG. 126** during the time required for healing, urine, fluids and/or clotted material may be drained out of bladder **1** via drainage holes **2018** in positioner **2013**, and flow past end cap **2020** of rod **2019** through flutes **2021** in end cap **2020** (shown in enlarged perspective view in **FIG. 127**), and generally out of the patient via inner tube **2011**. As shown in **FIG. 128**, the instrument may be connected via tubing to a urine collection bag **2023**.

[0415] It will be appreciated by those skilled in the art of design of mechanical surgical devices that the positioner need not be limited to the embodiment made of flexible and elastic polymeric shape memory material as described herein, but that alternative designs for such positioner are possible, which cause the positioner to alternately assume a retracted position and a deployed position, the deployed position suitable for catching in the bladder opening and urging the bladder into contact with the pelvic floor, in response to forces exerted or transmitted by tubes or other members. The positioner may comprise, for example, any of the positioner assemblies depicted in **FIGS. 14, 19, 24** and **57**, and described hereinabove. Similarly, it will be appreciated by those skilled in the art of design of mechanical surgical devices that the lodging member need not be limited to the hollow pre-folded polyurethane member described herein, but that alternative designs for such lodging member are possible, which cause the lodging member to alternately assume a retracted position and a deployed position, the deployed position presenting one or more ribs or projections that enable the lodging member to lodge within the urethra, in response to forces exerted or transmitted by tubes or other members.

[0416] As previously noted, the combination of tubes, positioner and lodging member may be configured in an instrument adapted for a retrograde anastomosis procedure, as described above, or configured in an instrument adapted for an antegrade procedure, as will now be described. In an antegrade procedure, instead of being inserted upwardly through the urethra, and into the bladder opening proximate the site of excision of the prostate, the instrument is inserted downwardly through a small incision in the patient's abdomen, through a small incision on an upper surface of the patient's bladder, into the bladder, through the bladder

opening, and into the urethra opening. The small incisions in the abdomen and upper surface of the bladder may be made with a trocar and cannula assembly (not shown), and held open by the cannula for insertion of the instrument therethrough.

[0417] As shown in **FIG. 129**, an antegrade anastomotic instrument **2030** may comprise outer tube **2031**, first inner tube **2032** and second inner tube **2034**. Similar to the retrograde anastomotic instrument described previously, these tubes may be sized such that first inner tube **2032** can be placed and be longitudinally movable within outer tube **2031**, and second inner tube **2034** can be placed and be longitudinally movable within first inner tube **2032**. First inner tube **2032** may have one or more drainage passages **2033** at its distal end. Second inner tube **2034** may have one or more drainage passages **2035** at its distal end.

[0418] End cap **2036** may be affixed to the distal end of second inner tube **2034**. As shown, end cap **2036** may have a rounded distal end that facilitates insertion of the instrument, and an extended section **2037** that terminates at rim **2038**.

[0419] As shown in **FIG. 129**, instrument **2030** may also comprise lodging member **2013**, which may be similar to the lodging member of the retrograde anastomotic instrument previously described, and can also be configured as shown by way of example in **FIGS. 131-133**. Referring again to **FIG. 129**, lodging member **2013** may be affixed at its proximal end to the distal end of first inner tube **2032** (at point A as shown), and is affixed at its distal end to extended section **2037** of end cap **2036** beneath rim **2038** (at point B as shown). Thus, it can be appreciated that moving second inner tube **2034** longitudinally with respect to first inner tube **2032** will cause either, alternately, longitudinal extension, or longitudinal compression of lodging member **2013**, and that extension of lodging member **2013** will cause ribs or projections presented thereby to retract into the pre-deployment position, and compression of lodging member **2013** causes ribs or projections presented thereby to extend to the deployed position (shown in **FIG. 129**), in a manner substantially similar to that of the lodging member of the retrograde anastomotic instrument previously described.

[0420] Antegrade anastomotic instrument **2030** also comprises positioner **2017**. Similar to the positioner of the retrograde anastomotic instrument previously described, in its pre-deployment position positioner **2017** may be substantially cylindrical. The pre-deployment shape of positioner **2017** facilitates insertion of the instrument. Positioner **2017** may be made of a suitable elastic and flexible polymeric material having shape memory, manufactured so as to be biased to normally assume a transversely-oriented shape as shown in **FIG. 129**, upon retraction of first inner tube **2032** relative to outer tube **2031**. Positioner **2017** may be affixed at its proximal end to the distal end of outer tube **2031** (at point C as shown in **FIG. 129**), and may be affixed at its distal end to the distal end of first inner tube **2032** (at point A as shown as **FIG. 129**).

[0421] Thus, it can be appreciated that longitudinal movement of outer tube **2031** with respect to first inner tube **2032** will cause positioner **2017** to assume its retracted, pre-deployment cylindrical position (similar to that shown in **FIG. 122**), or its deployed position as shown in **FIG. 129**.

[0422] As shown in **FIG. 129**, positioner **2017** may have, situated thereabout, one or more drainage holes **2018** which can permit urine, fluids or clotted material to drain, through drainage passages **2033** in first inner tube **2032**, though drainage passages **2035** in second inner tube **2034**, and into second inner tube **2034**.

[0423] A method for performing anastomosis of a patient's bladder and urethra using the above-described antegrade anastomotic instrument, following a prostatectomy, will now be described, with reference to **FIG. 2** for identification of parts of the patient's anatomy and **FIG. 129** for identification of parts of the instrument. Following a prostatectomy, the patient's bladder **1** and urethra opening **6** are separated by a void formerly occupied by the prostate, as shown in **FIG. 2**. It is necessary to connect the bladder I with the urethra **5** with bladder opening **4** and urethra opening **6** aligned, to restore urinary functions after recovery and healing.

[0424] A cannula with a trocar (not shown) is inserted into the patient's abdomen, and through an upper surface of the patient's bladder. The trocar is then removed and the cannula is left in place. The antegrade anastomotic instrument in its pre-deployment position is inserted into the cannula, until the entire positioner **2017** is within the bladder lumen. The surgeon then may move outer tube **2031** in a distal direction with respect to first inner tube **2032**, or alternatively or simultaneously, move first inner tube **2032** in a proximal longitudinal direction with respect to outer tube **2031**. This relative movement of the outer tube **2031** and first inner tube **2032** will permit positioner **2017** to assume its transversely-oriented position, shown in **FIG. 129**. The surgeon then may manipulate the instrument to locate the bladder opening **4** with end cap **2036**, and insert end cap **2036** through bladder opening **4**. Positioner **2017** in its deployed position will contact bladder wall **2** and catch in bladder opening **4**, and cannot pass therethrough. The surgeon then may manipulate the instrument to urge bladder wall **2** surrounding bladder opening **4** downward toward pelvic floor **7**, and further manipulate the instrument to locate urethra opening **6**, and insert end cap **2036** into urethra opening **6**. Thus, bladder wall **2** surrounding bladder opening **4** may be urged into contact with pelvic floor **7** surrounding urethra opening **6**, with bladder opening **4** and urethra opening **6** aligned. Next, holding outer tube **2031** and first inner tube **2032** immobile, the surgeon may retract second inner tube **2034** proximally. This will cause longitudinal compression of lodging member **2013**, so that it will assume the position shown in **FIG. 129**, and lodge within the urethra.

[0425] Those skilled in the art of design of mechanical surgical devices will appreciate that a variety of simple mechanical devices may be configured to operate and hold outer tube **2031**, first inner tube **2032** and second inner tube **2034** by actuation and manipulation at the proximal end of the instrument as required by the above steps, and so as to operate the instrument and hold it in the lodged position, including the handle assembly depicted in **FIGS. 83 and 85** and described above, or a variation thereof.

[0426] In the lodged position, the instrument may be used to hold the bladder wall **2** surrounding the bladder opening **4** in contact with the pelvic floor **7** surrounding the urethra opening **6** with bladder opening **4** and urethra opening **6** aligned, during the period of time necessary for these tissues to knit and heal together naturally.

[0427] While the instrument is lodged in position during the time required for healing, urine and other fluids may be

drained out of bladder **1** via drainage holes **2018** in positioner **2017**, through drainage passages **2033** and **2035**, and generally out of the patient via second inner tube **2034**. As shown in **FIG. 129**, the instrument may be connected via tubing to a urine collection bag **2023**.

[**0428**] **FIG. 130** depicts an alternative embodiment of instrument **2030**. As compared with the embodiment depicted in **FIG. 129**, first inner tube **2032** may be reduced in radius and second inner tube **2039** may be a rod. Second inner tube **2039** may terminate at its distal end with end cap **2036**, having rim **2038** and extended section **2037**. Use and function of the instrument depicted in **FIG. 130** may be substantially similar to use and function of the instrument depicted in **FIG. 129**, except that following deployment and lodging of the instrument, urine and other fluids can be drained from the bladder through drainage holes **2018** in positioner **2017**, and directly into outer tube **2031**, which is connected to urine collection bag **2023**, eliminating the necessity for additional drainage passages **2033**, **2035** in internal tubes within the instrument as shown in **FIG. 129**.

Other Refinements

[**0429**] The exemplary embodiments described herein for an instrument in accordance with the present invention comprise one or more tubes and/or rods, used for the translation of forces and movement from a proximal handle assembly to an assembly or assemblies proximate to a distal end of an instrument, and also, potentially, used as catheters for, among other purposes, the transmission of gas or fluid pressure, and the draining of urine or other fluids during recovery and healing. The inventors have determined that nitinol, which when suitably treated and formed, has combined properties of strength, flexibility, elasticity, stiffness, hardness and biocompatibility that make it suitable as a material for such members, by way of example. Other materials may suffice, particularly when one or more of the above-mentioned properties may not be so stringently required. Thus, for example, a polymer such as styrene might be used where it is not necessary, for example, to translate force and movement (such as, for example, when the tube functions only as a catheter). Of course, any other materials having the necessary properties for the particular application may be used.

[**0430**] With respect to instruments designed for a retrograde post-prostatectomy bladder-urethra anastomosis procedure such as described herein, it may be desirable to have a bend angle in the tube assembly, such as in tube assembly **500 (FIG. 3)**, tube assembly **3200 (FIG. 134)**, or other tube assembly supporting an end effector. A bend proximate to the end effector assembly, of about 80 to about 90 degrees (expressed as the angle at which a distal portion of the tube assembly is bent away from a straight axis projected distally from a proximal portion of the tube assembly), and preferably about 85 degrees (wherein the tube assembly defines an obtuse angle of about 95 degrees), may be desirable. Such a bend angle may serve to better facilitate manipulation of the instrument within the anatomical architecture involved in the procedure, and facilitate control of the positioning of the end effector assembly within the bladder lumen to enable driving anchors at a desired or selected angle with respect to the pelvic floor.

[**0431**] In order to be most effective at operating within the limited space provided by the anatomical architecture involved in a procedure to effect anastomosis of the bladder and urethra following a prostatectomy, it is desirable that the end effector assembly, including any positioner assembly, anchor driver assembly and/or end cap or harness assembly, be limited in length. Preferably, but not by way of limitation, the length of the end effector assembly, following opening of the positioner, will be less than about 2 inches, and more preferably, less than about 1 ½ inches, from the proximal surfaces of the positioner when opened to the distal end of the instrument. For similar reasons, for an instrument of the present invention designed for use in a retrograde procedure (involving insertion upwardly through the urethra), the size of the urethra and other anatomical features make it preferable that the end effector and the tube assembly be limited to a diameter of about 28 french, or about 9.3 millimeters.

[**0432**] The inventors also have determined that it may be advantageous for an instrument configured for retrograde insertion (upwardly into and through the urethra) to have a detachable and reattachable, or detached and attachable, end effector assembly. For example, if the end effector assembly (comprising a positioner assembly and an anchor driver assembly such as positioner **400** and anchor driver **300** shown in **FIG. 3**, shuttlecock assembly **800** shown in **FIG. 17**, umbrella assembly **900** shown in **FIG. 22**, or end effector assembly **3400** shown in **FIG. 134**) is detached from and attachable to the supporting tube assembly or other supporting longitudinal member assembly, the end effector assembly may be separate or detached from the supporting assembly prior to insertion. The supporting assembly may then be inserted through the urethra without the end effector assembly, which may ease insertion and eliminate the possibility for components of the end effector assembly, otherwise attached, to catch or cause tissue damage within the urethra during insertion. Upon insertion, and after the distal end of the supporting assembly is past the urethra and/or above the pelvic floor, the end effector assembly may be introduced into the patient's abdomen via a cannula through the abdominal wall, and attached to the supporting assembly for use in the anastomosis procedure, using any suitable means of guidance such as an endoscope, external imaging techniques and/or tactile feel. It can be appreciated that the supporting assembly and the end effector assembly can have a variety of designs that enable operable connection of their respective structural and operational members to effect attachment and operability of the end effector assembly.

[**0433**] Tubes, rods or other members that are to be inserted and/or remain inside the patient for a substantial period of time during the anastomosis procedure, such as but not limited to central rod or guide wire **3230**, catheter tube **3510 (FIGS. 141-144)** and/or other components may be provided with an antimicrobial coating, such as that described in copending U.S. Patent Application Publication No. 2004/0220614. Additionally or alternatively, such components may be provided with a hydrophilic or other friction-reducing coating.

[**0434**] Several embodiments of a method for effecting anastomosis of the bladder and urethra following a prostatectomy, as depicted and described herein, involve the driving of anchors into the pelvic floor. In such a procedure it may be desirable for anchors to be driven into the pelvic floor in locations that avoid sensitive areas and thus reduce the potential for complications. For example, referring to **FIG. 147**, it may be desirable to avoid driving anchors into areas

proximate to the dorsal veins D of the penis, other neurovascular bundles N, the rectum R, or other sensitive anatomical features. Accordingly, referring to **FIG. 147**, the inventors have determined that anchors are preferably driven into the pelvic floor at locations within the zones of about 8 to about 10 o'clock, and about 2 to about 4 o'clock, about the urethra U, as shown at "A" and "B" respectively in **FIG. 147**. More preferably, as may be the case, for example, with use of the balloon and harness systems depicted and described herein, two anchors are driven into the pelvic floor at locations at about 9 and about 3 o'clock about the urethra.

[0435] It also is important, when using an instrument of the present invention to install anchors, to avoid driving anchors into, through or across the ureteric orifices of the bladder. The various embodiments of an instrument described herein facilitate avoidance of this event.

Anchors

[0436] As described herein, anchors **700** or other suitable fasteners perform a holding function, holding the bladder wall to the pelvic floor and/or holding a harness to the bladder wall and/or pelvic floor. Each of the anchoring and/or fastening features discussed herein is only exemplary of a large number of designs and configurations possible within the scope of the invention.

[0437] An anchor **700** or other fastener may have one or more suitable lodging structures that function to cause the anchor to lodge in tissues after being driven thereinto, so as to resist withdrawal from the tissues. Such lodging structures may comprise barbs, circumferential ridges, projections or any other features effective to cause the anchor to lodge in the tissues when driven into them. The size, shape and number of suitable lodging structures may vary. Additionally, the inventors have determined that, whenever barbs are included on an anchor it may be desirable when manufacturing such an anchor, to round off, or radius, the protruding ends of the barbs (as viewed from the anchor forward end), in order to reduce the possibility that the barbs will snag on loose bladder wall tissue during insertion and opening of an anchor driver assembly, on which the anchor is loaded, inside the bladder.

[0438] An anchor or other fastener may also have a head or other suitable penetration-limiting structure that may function to limit the depth to which the anchor or other fastener may be driven and may also function to assist in securing proximal tissues to underlying, distal tissues. It will be appreciated that such a penetration-limiting structure need not necessarily be located at the rearward end of an anchor shaft to be effective.

[0439] It may be desirable that the forward end of an anchor be pointed or have a chisel-like shape, to facilitate more effective and/or less damaging penetration of tissues. Additionally, the inventors have determined that a point formed on the forward end of a cylindrical anchor shaft comprising three sloping flat faces in planes intersecting each other at equal angles, facilitates penetration of the anchor into tissues in a manner that minimizes the potential for the anchor to veer off-target or off-direction during driving.

[0440] When used to secure the walls of the bladder to the pelvic floor, it may be desirable for anchors to be of a length sufficient to penetrate through the bladder walls and the fascia layer of the pelvic floor. For example but not by way of limitation, such anchors are preferably about ½-inch to 2½-inches in length. For anchors that are to be installed near the rectum, it may be desirable for them to be at the shorter end of the preferred range of length.

[0441] Anchors **700** or other suitable fasteners may be formed from a substantially biocompatible polymer or metal. Where shape memory and elasticity may be desired, anchors may be manufactured using elements made of an elastic material, such as an elastic metal alloy or a thermally activated or activatable alloy, such as a nickel-titanium alloy (for example nitinol) or stainless steel alloy, so that the anchors or other fasteners may be preformed and biased with shaped ends or barbs along the shaft, which can be deployed by pushing them out of an instrument so that when they pass into the target tissue, they resume their shape within the target tissue.

[0442] If bioabsorbability is desired, anchors **700** or other suitable fasteners may be formed of a suitably substantially biocompatible and bioabsorbable material. The inventors have determined that flexible absorbable polymers (e.g., polydioxanone polymers, or polymers containing lactides, glycolides, polyglactin, etc., such as the polymers marketed by Johnson & Johnson and/or Ethicon, Inc. under the trademarks "Vicryl" and "PDS II") are potentially suitable materials. Other bioabsorbable materials having the necessary physical properties may be used.

[0443] When used to anchor harness straps for a balloon and harness system such as depicted and described herein, bioabsorbable anchors may be used to provide a bioabsorbable harness release mechanism that avoids the necessity for, or reduces the importance of, a structure or device capable of attaching a harness to, and then releasing a harness from, an anchor by mechanical means. By way of example but not of limitation, referring to **FIG. 145**, it can be appreciated that if a structure such as harness hook **760** on anchor **700** is bioabsorbable, with a time degradation characteristic that corresponds to the time required for the anastomosis procedure, the degradation and dissolution of harness hook **760** through bioabsorption will serve to release harness **3430**, facilitating removal from the patient.

[0444] Additionally, there may be situations when the control of the degradation and absorption profile and/or particle breakup size of a bioabsorbable anchor or other suitable fastener may be desirable. For example, should one or more pieces of a bioabsorbable anchor, such as, for example, the head of an anchor, break away in a large piece as the anchor material is degrading after deployment, it could cause a blockage. Accordingly, bioabsorbable anchors or other suitable fasteners may be designed and manufactured in a manner in which degradation rates and particle breakup size may be controlled. For example, a bioabsorbable anchor or other fastener may be formed with a cast, molded, embossed or machined-in arrangement of scoring, perforation, or grooving that creates areas of reduced thickness and increased stress of the part in selected locations, encouraging earlier fracture proximate to such areas for the purpose of reducing the size of portions that may break away as the material degrades. Alternatively, or additionally, a bioabsorbable anchor or other fastener may be formed of joined materials, or comprise joined components, having

differing degradation/absorption profiles such that zones of faster and slower degradation within the part may be created, such that the possibility of breakaway and release within a body lumen of pieces that are large enough to create a possibility of blockage or other adverse effect is reduced.

[0445] An anchor shaft may be hollow so as to slidably fit over a driver pin, and be substantially releasably held thereon by friction fit or any other suitable means. Alternatively, an anchor may have a solid shaft wherein a driver pin pushes against the proximal end of the anchor or alternatively, fits over the proximal end of the anchor and releasably grips it by friction fit or any other suitable means.

[0446] It would be apparent to a person having skill in the art field that there are various designs for anchors that would be effective for anchoring the bladder to the pelvic floor over the urethra opening. Anchors may be provided that have a plurality of shafts, barbs and tips operatively linked to a driver assembly. It is not necessary that the anchors are individual anchors, only that each anchor's size and shape, alone or in combination, are sufficient to effect and maintain contact between proximal and underlying, distal target tissues for an appropriate period of time.

[0447] In still a further embodiment, an anchor may be formed of a bimetallic or other combination of at least two materials having differing expansion properties, that will cause the part formed therefrom to take a desired shape after heating, for example, by the patient's body. In such a case, the anchor would be supplied in a cold or room-temperature state and then allowed to attain the final desired shape after installation, when heated by the patient's body.

[0448] Although nitinol may be used in this service because of its physical properties and its significant history in implantable medical devices, it may also be suitable for use as an anchor because of its overall suitability for use in conjunction with or contemplation of use of magnetic resonance imaging (MRI) technology.

[0449] In summary, numerous benefits are apparent which result from employing the concepts of the invention. The foregoing description of one or more embodiments of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiments were chosen and described in order to best illustrate the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to best utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be limited only by the claims appended hereto.

We claim:

1. A hand-operated device for holding, and effecting relative driving and retraction longitudinal movement between, two members of a medical instrument, comprising:

a handle member, having a longitudinal guide defining a longitudinal line of travel, and a longitudinal groove that has a pair of opposing surfaces parallel to said line of travel, said longitudinal groove also having first and second ends, and a detent catch in one of said opposing surfaces;

a moving member fitting and residing in said longitudinal guide, and longitudinally movable therewithin along said line of travel with respect to said handle member, said moving member having therein first and second pawl receiving slots lying along a second line substantially parallel with said line of travel;

a driving trigger member, further comprising

a fulcrum member residing in said longitudinal groove of said handle member and movable alongtherein, and adapted to be releasably captured by said detent catch,

a pawl in operable proximity to said moving member and adapted be insertable into either of said pawl receiving slots when said moving member is moved within said longitudinal guide to align either of said pawl receiving slots with said pawl,

and a trigger portion,

wherein said pawl and said trigger portion move about said fulcrum member, and said pawl moves about said fulcrum member, toward or away from said moving member;

a pawl actuating spring in operable connection with said handle member and said driving trigger member so as to urge said pawl toward said moving member;

a detent spring in operable connection with said handle member and said driving trigger member so as to urge said fulcrum member toward said detent catch when said fulcrum member and said detent catch are operably aligned;

a driving spring in operable connection with said handle member and said movable member so as to urge said moving member to move within said longitudinal guide along said line of travel.

2. The device of claim 1 wherein said pawl actuating spring and said detent spring comprise a single spring.

3. The device of claim 2 wherein said single spring is a torsion spring.

4. The device of claim 1 wherein said trigger portion further comprises a retraction member.

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